PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 17/00

A1

(11) International Publication Number: WO 92/13490

(43) International Publication Date: 20 August 1992 (20.08.92)

(21) International Application Number: PCT/US92/00658

(22) International Filing Date: 5 February 1992 (05.02.92)

(30) Priority data:
650,869 5 February 1991 (05.02.91) US

(60) Parent Application or Grant
(63) Related by Continuation
US 650,869 (CIP)
Filed on 5 February 1991 (05.02.91)

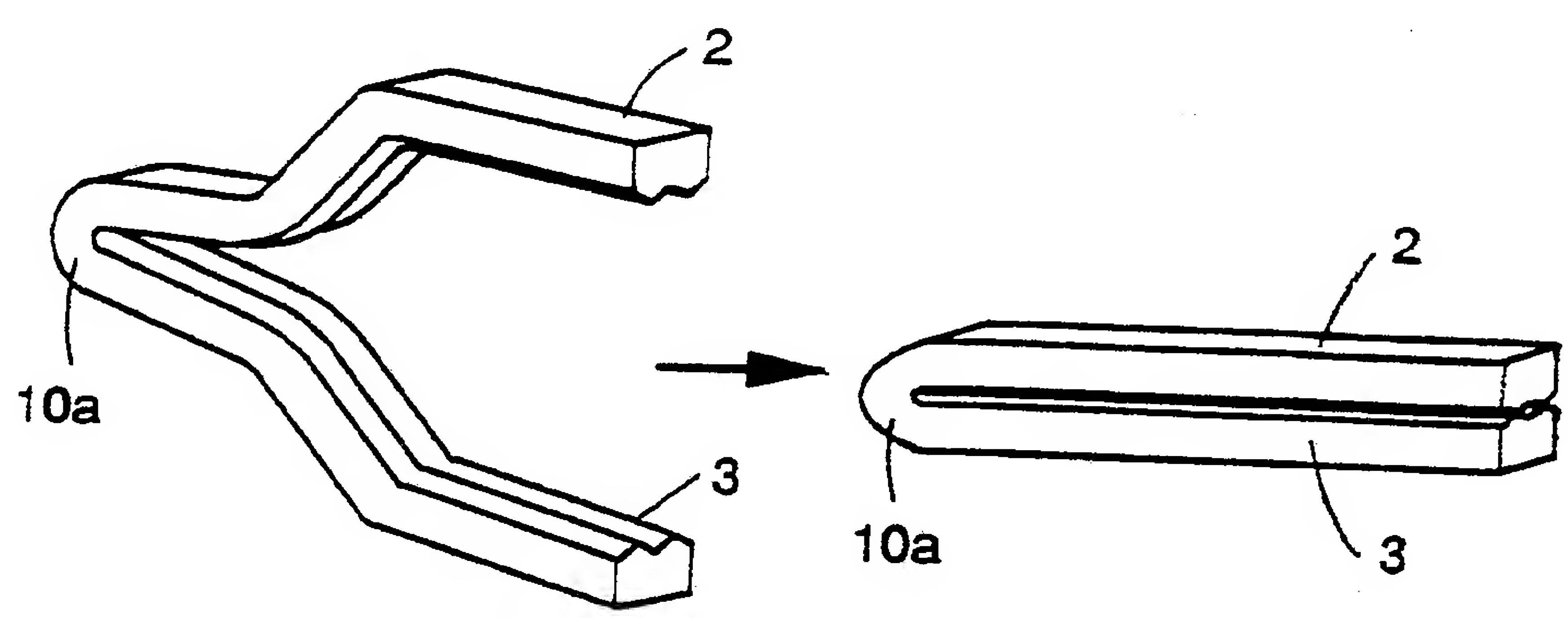
(71)(72) Applicant and Inventor: FRIEDLAND, Thomas, W. [US/US]; 2132 Dellesta Drive, Bellingham, WA 98226 (US).

(74) Agent: PETERSON, James, W.; Burns, Doane, Swecker & Mathis, George Mason Building, Washington and Prince Streets, P.O. Box 1404, Alexandria, VA 22313-1404 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, KR, LU (European patent), MC (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.

(54) Title: SURGICAL CLIP FORMED OF SHAPE MEMORY ALLOY



(57) Abstract

A surgical fastening clip (1) of a shape memory alloy which applies a first clamping force to a site when the alloy is in its martensitic condition and a second clamping force to the site when the alloy heats due to surrounding tissue such that the alloy transforms to its austenitic condition. The second clamping force is greater than the first clamping force and prevents the clip from slipping or falling off the clamped site due to shrinkage or movement of the site. A method of using a surgical fastening clip of the invention and methods of making such clips formed of a shape memory alloy are also disclosed.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark	MG	Madagascar		
ES	Spain				

SURGICAL CLIP FORMED OF SHAPE MEMORY ALLOY

Background of the Invention

Field of the Invention

The present invention relates to an improved surgical fastening clip, a method for the production thereof and a method of using the surgical fastening clip. In particular, the surgical fastening clip is formed of a shape memory alloy which provides a clamping force even when the object being clamped shrinks, thins out or moves. The device may change shape to project "teeth" into the object to further enhance its grasping and non-slip capabilities.

Description of the Prior Art

Various medical devices formed of shape memory alloys are known in the art. For instance, U.S. Patent No. 4,170,990 ("Baumgart") discloses a method for implanting and subsequently removing mechanical implants of an alloy which exhibits a memory effect, the implant being removed by cooling it to a temperature below the temperature which actuates the memory effect. Baumgart discloses that such implants can include nails, wires, sutures, clamps, clips, sleeves, rings, discs, pins or tubes. Baumgart further discloses that separation in living tissue can be fixed by rotating, compressing, bending or twisting of the implant by utilization of the memory effect. Accordingly, changes in shape when the implant is used

result solely from temperature changes. Baumgart does not disclose a surgical fastening clip of a shape memory alloy which is mechanically deformed such that the legs of the clip clamp an object therebetween.

U.S. Patent No. 4,665,906 ("Jervis") discloses medical devices of shape memory alloys which exhibit stress-induced martensite at body temperature. In particular, a shape memory alloy at a temperature between M_s and M_d but below A_s is initially austenitic, and application of a stress exceeding σ_M forms stress-induced martensite until the alloy becomes fully martensitic, after which application of further stress causes the alloy to deform elastically and then plastically. If the stress-induced martensite is not plastically deformed, release of the stress allows the martensite to recover elastically so as to have zero residual stress but a non-zero residual strain. Heating the alloy above A_s results in reversion to austenite, and if the alloy is unrestrained, the original shape will be recovered. If not, it will be recovered to the extent permitted by the restraint. Upon cooling to the temperature at which the alloy was deformed (or a temperature at which stress-induced martensite is seen), the stress produced by the alloy will be constant. The alloy can thus provide a constant force over a strain range of about 5%.

Alternatively, at a temperature between M_s and M_d but above A_s, upon application of stress the alloy deforms elastically and when the stress exceeds σ_M forms stress-induced martensite after which the martensite is deformed, as described above. The unloading behavior is different from that described above in that the alloy recovers elastically at first until an essentially constant critical stress σ_A is

reached at which point the alloy reverts to austenite without requiring a change in temperature. Then, if the stress is removed from the reverted austenite it recovers elastically. The alloy can thus provide a constant force over an effective working range of about 5%.

Jervis discloses a shape memory alloy ring for holding a sewing cuff to the body of an artificial heart valve. Jervis discloses that such a ring had previously been described as being made in the austenitic state, cooled to the martensitic state, deformed, placed around the valve body and heated to cause reversion to austenite. According to Jervis' invention, the ring is made in the austenitic state, cooled to the martensite phase, expanded, placed around the valve body, heated above A_f and cooled, whereby a constant force is applied to the valve body. Jervis also discloses bone staples, clips, etc. made of a shape memory alloy. In particular, Jervis discloses a staple made of an alloy below A_s which is for holding fragments of bone together, the staples being placed in the martensitic state, heated to the austenitic state and cooled to body temperature to achieve constant force. Above A_s, the staple is held in the deformed position by a moderate force and then released after insertion to provide an accurately-known force. This allows easier removal by deformation which forms stress-induced martensite.

U.S. Patent No. 4,556,050 ("Hodgson") discloses an artificial sphincter which includes an implantable clamp for selectively pinching closed or opening a vessel in a living body. The clamp includes a spring member and a shape memory member. One of the opening and closing operations is effected by deforming

the shape memory member from the memory configuration, and the other of the operations is effected by heat recovering the shape memory member to the memory configuration by heating above body temperatures. Heating is accomplished by means of an ac source via a coil in the shape memory member.

U.S. Patent No. 4,485,816 ("Krumme") discloses a surgical staple which is formed into a desired closed position at a temperature above the transition temperature and then cooled below the transition temperature before deforming it into an open position, the resulting staple reverting to its closed position when it is subsequently reheated by means of an electrical power supply above the transition temperature, the transition temperature being in the range of 50-80°C.

Other medical devices of shape memory alloys are disclosed in U.S. Patent No. 3,786,806 ("Johnson") which discloses a plate formed of a shape memory alloy for drawing fractured bone ends together, U.S. Patent No. 4,233,690 ("Akins") which discloses a prosthetic element of a shape memory alloy which can be used as a coupling element, U.S. Patent No. 4,490,112 ("Tanaka") and U.S. Patent No. 4,037,324 ("Andreasen") which disclose components of shape memory alloys having dental applications, and Soviet Union Publication No. 1,110,447 which discloses a compressing fixator of a shape memory alloy for use in healing bone fractures.

Various types of surgical clips are known in the art. For instance, U.S. Patent No. 4,844,066 ("Stein"), U.S. Patent No. 4,834,096 ("Oh"), U.S. Patent No. 4,696,396 ("Samuels") and U.S. Patent No. 3,363,628 ("Wood") disclose various types of surgical

clips. Five manufacturers sell hemoclips in the United States; such manufacturers include Ethicon (Johnson & Johnson), Weck (Squibb), Richard Allen, Pilling (Japanese) and Auto Suture.

Surgical fastening clips (or hemoclips) are currently used in surgery to prevent bleeding by squeezing vessels and tissue. The clips are left in the body at the conclusion of the operation. Conventional clips are made of malleable stainless steel, titanium or tantalum and are squeezed together on the tissue by plier-like forceps. The metal clip is thus closed by plastic deformation. All of the commercially available clips will frequently slip off the tissue during or shortly after completion of surgery, thereby lessening their effectiveness and decreasing their use to situations wherein a slipping clip is not a vital problem.

The alternative to clipping is suture ligating which is more secure but takes much longer to do. There are many situations wherein all surgeons refuse to use surgical fastening clips because they are not secure enough, and many surgeons simply do not use the clips at all because of their unreliability.

All of the conventionally available clips have some "spring back" when they are squeezed together which then results in the two legs of the clip not lying in opposition but actually having some gap therebetween. Such clips also will not follow tissue as it shrinks in thickness; thus, with such clips there will not be a continuing squeezing force to keep the clip on the tissue. The present invention overcomes a major drawback of the existing clips -- their unreliability.

Summary of the Invention

According to the present invention, a surgical fastening clip is provided which can be applied in a manner similar to existing conventional clips. The clip of the invention, however, comprises a shape memory alloy which undergoes a shape memory effect when the alloy is heated into the austenitic state. In this state, the clip exerts a squeezing force on the tissue which will continue to close the clip and follow the tissue as it thins out.

The clip, according to the invention, can include interdigitating teeth along the arms and the end thereof that will dig into the tissue, thereby greatly increasing its resistance to slip and thus also making it far more secure. The clips of the invention will be more dependable and will be usable in more situations than the existing conventional clips. They can also be made in larger sizes and could replace surgical stapling devices.

In accordance with the invention, a surgical fastening clip is provided as a substantially U-shaped member of a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensite state and an austenite transformation temperature above which the alloy transforms to its austenite state. The clip is deformable in its martensitic state from a first configuration to a second configuration and recovers to the first configuration when heated to transform the alloy to its austenitic state. The clip is open and capable of being deformed in its martensitic state so as to apply a first clamping force on an object and so as to apply a second clamping force on the object when

the alloy is heated to transform it to its austenitic state, the second clamping force being greater than the first clamping force.

The clip will be squeezed onto the object tissue by a pliers-like device using plastic deformation of the metal of the clip in the manner in which existing clips are applied. As the clip then rises to body temperature, it passes through its shape memory transition temperature and attempts to return to the shape in its memory. This causes the two legs of the clip to attempt to move closer together, thus exerting an increased clamping force on the object. The clip may also change shape to form interdigitating corners or "teeth" that press down into the tissue, thus further enhancing its gripping power. The ends of the arms may also bend down into the tissue preventing the clip from slipping back off the tissue. If the clip forms a "zig-zag" shape, as one design may, the effective length of the arms will shorten and thereby bunch up the tissue, making it thicker and easier to grip. The legs can be straight when the clip is in its martensitic state and the legs can have an undulating, zig-zag or curved shape, and/or the legs can move past each other when the alloy is heated and transforms to its austenitic state. The clip can comprise a piece of wire having a non-circular cross-section, and the alloy can comprise a Ni-Ti based shape memory alloy having an austenitic transformation temperature in the range of 30 to 35°C. The cross-section can include a flat portion and at least one curved portion, e.g., a heart-shaped cross-section. The clip can include a connecting portion interconnecting the legs, the connecting portion being V-shaped, U-shaped or Y-shaped.

The connecting portion may not exhibit a shape memory effect when the clip is deformed from the open configuration into the closed configuration and the alloy is heated into its austenitic state. That is, the shape memory may be destroyed from excessive plastic deformation of the connecting portion when the clip is deformed from the open configuration to the closed configuration.

A superior clamping, clipping or fastening device will lend itself to new applications in surgery. It will be possible to use the device to connect together portions of intestine, arteries, veins, tendons or other tissues that are presently sutured together by sutures or stapling devices. Increased confidence of the clip as a surgical fastening clip will allow its use as a surgical fastening device for major (larger) arteries and veins where prudence prevents the existing clips from being used.

In accordance with another feature of the invention, a method of making the surgical fastening clip is provided. In particular, the method comprises: (i) providing the alloy in the form of an elongated member; (ii) forming the member into a clip having a substantially U-shaped configuration with two spaced-apart opposing legs extending in a longitudinal direction; (iii) deforming the clip such that the opposing legs are squeezed together in a closed configuration; (iv) heating the clip in the closed position such that the alloy transforms to its austenitic state; (v) cooling the clip such that the alloy transforms to its martensitic state; and (vi) deforming the clip such that the legs are moved away from each other from said closed configuration to an open configuration. The clip can be heat-treated in

one or more steps during the process of making the clip. Step (iii) can further include forming at least one projection on at least one of the legs such that when the clip is in its closed configuration the projection extends through a plane extending between the legs, or step (iii) can include forming a plurality of projections on each of the legs such that when the clip is in its closed configuration the projections inter-engage. Alternatively, step (iii) can include forming each of the legs with at least one bend along a length thereof, and step (vi) can further include straightening each of the legs such that the legs are elongated in said longitudinal direction.

Another method of making a surgical fastening clip in accordance with the invention includes (i) providing an elongated member of a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state; (ii) bending the member into a non-linear configuration; (iii) heating the member in the non-linear configuration such that the alloy transforms to its austenitic state; (iv) cooling the member such that the alloy transforms to its martensitic state, the non-linear configuration being retained during the cooling of the member; and (v) plastically deforming the member into a surgical fastening clip having first and second legs interconnected at one end thereof by a connecting portion of the clip. The member can comprise a wire, and step (ii) can be performed by helically winding the wire on a mandrel, the wire being straightened between steps (iv) and (v). After the straightening step, the wire can be wound onto a spool and fed through clip-making machinery wherein step (v) is performed. In

addition, step (ii) can include forming undulations in the wire, and the undulations can be removed by straightening the wire between steps (iv) and (v). According to another feature of the invention, the process can include placing the connecting portion in a heat sink, plastically deforming free ends of the legs such that they are bent, heating the free ends of the legs such that the free ends transform to the austenitic state, cooling the free ends such that the free ends transform to the martensitic state and straightening the free ends.

In accordance with another feature of the invention, a method of in vitro clamping of living tissue is provided. This method includes: (i) placing opposed legs of the surgical fastening clip of the invention which is in an open configuration around a site of living tissue; (ii) pressing the legs together to the closed configuration; and (iii) heating the clip such that the alloy transforms to its austenitic state and the legs are urged together due to the shape memory effect of the shape memory alloy. Step (ii) can be performed at an ambient temperature or at a temperature in the range of 20 to 25°C. Then the clip undergoes the shape memory effect by heating in step (iii) to a temperature of less than 37°C, such as 30 to 35°. Step (ii) can be performed with surgical pliers, the pliers having a pair of pivoted jaws which press the legs of the clip together. The method can also include a step (iv) of moving the legs closer together in response to shrinkage of the site which would otherwise cause the clip to become loosened; step (iv) being accomplished due to a self-biasing force urging the legs together as a result of the shape memory effect. If the legs have a first length in a longitudinal direction and the clip includes at least one bend in each of the legs when the alloy is in its austenitic state and the legs have a second length in the longitudinal direction without a

bend when the alloy is in its martensitic state with the second length being greater than the first length, step (ii) will result in the legs being pressed together without the bend in each of the legs, and step (iii) will result in the corner of the bend in one of the legs being pressed in the longitudinal direction against the inside of the bend in the other leg thereby forming a locking or gripping of the tissue. Alternately, the corners could press together in an opposed fashion to grip the tissue.

The invention also provides a tool for making surgical fastening clips and applying them to an object. The tool includes a housing, support means for supporting wire in the housing, feeding means for feeding wire from the support means, forming means for forming wire fed by the feeding means into a shape of a surgical fastening clip, and applying means for applying a surgical fastening clip formed by the forming means to an object. The tool can include cutting means for cutting a section of wire fed by the feeding means, the forming means forming a section of wire cut by the cutting means into the shape of a surgical fastening clip. Wire can be supported by the support means, and the wire can comprise a spool of wire. The wire can comprise a Ni-Ti based shape memory alloy which has been heat-treated to have a memorized non-linear configuration and subsequently plastically deformed in its martensitic condition from the non-linear configuration into a second configuration different from the non-linear configuration. The non-linear configuration can comprise a helical shape and the second configuration can comprise a generally rectilinear shape, and/or the non-linear configuration can comprise an undulating wire and the second configuration can comprise a wire without undulations.

Brief Description of the Drawing

The invention will now be described with reference to the attached drawing, in which:

FIG. 1 shows a surgical fastening clip according to the invention in an open configuration;

FIG. 2 shows the clip of FIG. 1 in the closed configuration;

FIG. 3 shows a transverse cross-section of the clip shown in FIG. 2;

FIG. 4 shows a side view of the clip shown in FIG. 1;

FIG. 5 shows a side view of the clip shown in FIG. 2;

FIG. 6 shows a perspective view of a plurality of clips in accordance with the invention mounted on a rack;

FIGS. 7-9 show alternative shapes for the surgical fastening clip according to the invention;

FIGS. 10-12 show various x-y dimensions for the surgical fastening clips in accordance with the invention;

FIG. 13 shows a further embodiment of the surgical fastening clip according to the invention prior to undergoing a shape memory transformation;

FIG. 14 shows a clip according to the invention after it undergoes a shape memory effect;

FIG. 15 shows a top view of a surgical fastening clip according to a further embodiment of the invention;

FIG. 16 shows a side view of the clip shown in FIG. 15;

FIG. 17 shows an end view of the clip shown in FIG. 16;

FIG. 18 shows an end view of the clip shown in FIG. 16 after the clip has undergone a shape memory

effect but with the arms separated for clarity of illustration;

FIG. 19 shows the clip of FIG. 18 in a closed configuration;

FIG. 20a shows a side view of a zig-zag type surgical fastening clip in accordance with another embodiment of the invention;

FIG. 20b shows a top view of the clip shown in FIG. 20a;

FIG. 20c shows an end view of the clip shown in FIG. 20a;

FIG. 21a shows a side view of the clip shown in FIG. 20a after application of the clip but before a shape memory effect takes place;

FIG. 21b shows an end view of the clip shown in FIG. 21a;

FIG. 22a shows a top view of the clip shown in FIG. 21a after the shape memory effect has taken place;

FIG. 22b shows a side view of the clip shown in FIG. 22a;

FIG. 22c shows an end view of the clip shown in FIG. 22a;

FIG. 23 shows a clip in accordance with the invention wherein the connecting portion is V-shaped;

FIG. 24 shows a clip in accordance with the invention wherein the connecting portion is Y-shaped;

FIG. 25 shows a clip in accordance with the invention mounted in a heat sink so that free ends of the legs can be differentially heat-treated;

FIG. 26 shows how a clip in accordance with the invention can be used to staple tissue together;

FIG. 27 shows how a clip in accordance with the invention can be used to fasten sutures;

FIG. 28 shows a tool in accordance with the invention for feeding a continuous length of wire,

cutting the wire, forming the wire into a clip and applying the clip; and

FIG. 29 shows another tool in accordance with the invention for feeding a continuous length of wire, forming the wire into a clip, cutting the wire and applying the clip.

Detailed Description of the Preferred Embodiments

The present invention provides an improved surgical fastening clip made of a shape memory alloy. The clip can be applied in the same manner as existing surgical fastening clips, that is, a pliers-like tool can be used to plastically deform the clip over a vessel or tissue of a living person or animal. Surgical fastening clips are typically used to stop bleeding during surgical procedures. However, a problem with existing conventional clips is that they have no ability to continue to exert a clamping force on the vessel or tissue as the vessel or tissue deforms, shrinks, moves, etc. as it responds to the clip and/or thins out as it loses fluid due to compression force. Accordingly, a drawback of existing conventional clips is that they frequently become loose or fall off, allowing bleeding to recur, and the clips may even fall into the surgical zone. The clip according to the invention solves the problem of loosening and/or falling off of conventional clips by using the shape memory effect to generate a continuous constant stress and, hence, constant or increasing pressure through the clip on the tissue or vessel even as the tissue or vessel deforms, shrinks, moves, etc.

One embodiment of the surgical fastening clip, according to the invention, is shown in FIG. 1. In particular, the clip 1 comprises a substantially U-shaped member of a shape memory alloy having a

martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state. The clip is deformable in its martensitic state from the first configuration, such as the closed configuration shown in FIG. 2, to a second configuration, such as the open configuration shown in FIG. 1. The clip recovers the first configuration when heated to transform the alloy to its austenitic state. As shown in FIG. 1, the clip is open and capable of being deformed in its martensitic state so as to apply a first clamping force on an object and so as to apply a second clamping force on the object when the alloy is heated to transform it to its austenitic state, the second clamping force being greater than the first clamping force. That is, when the clip shown in FIG. 1 is deformed in its martensitic state to the configuration shown in FIG. 2, upon heating the clip so as to transform it to its austenitic state, the clip which already is in its closed configuration exerts an even greater clamping force since legs 2, 3 of the clip attempt to move toward each other in the austenitic state.

The alloy selected for the shape memory alloy of the clip in accordance with the invention preferably transforms to its austenitic state at a temperature below 37°C. In accordance with a preferred embodiment of the invention, the alloy transforms to its austenitic state at a temperature in the range of about 32 to 35°C.

The clip of the invention can have various shapes. For instance, the clip can have the shape shown in FIGS. 1-5 wherein each of the legs is substantially V-shaped in lateral cross-section. For instance, each of the legs can include a pair of

longitudinally extending sections 4, 5, the sections being joined together at lower longitudinally extending edges thereof and being laterally separated from each other at upper longitudinally extending edges thereof, as shown in FIG. 3.

The clip can comprise a single flat strip of material which has been deformed into the U-shaped member. The flat strip of material can include longitudinally spaced-apart end sections 6, 7 forming the legs 2, 3 and a center section 8 therebetween, as shown in FIG. 4. The center section 8 has laterally spaced-apart edges which are closer together than laterally spaced-apart edges of each of the end sections 6, 7. As shown in FIGS. 1-3, each of the end sections can include a longitudinally extending V-shaped bend. The clips according to the invention can be packaged, as shown in FIG. 6, wherein a plurality of clips is provided on a suitable support member 9. Multiple clips could be stacked in an application device (not shown) where they would automatically advance one at a time to the open end of the device after the clip ahead is applied.

The clip 1 can have shapes other than those shown in FIGS. 1-5 wherein the V-shaped bend on leg 2 includes a pair of upper surfaces which face a pair of lower surfaces of the V-shaped bend on the other leg 3. For instance, the clip shown in FIG. 9 includes V-shaped bends which fit together in a complementary manner such that only one upper surface of the lower V-shaped bend on leg 3a faces one surface of the upper V-shaped bend on leg 2a. Alternatively, as shown in FIG. 8, one of the legs 2b can include a V-shaped bend which is substantially V-shaped in lateral cross-section, and the second leg 3b can be substantially rectilinear in lateral cross-section. In this case, the second leg 3b

includes a longitudinally extending edge thereof located intermediate opposed longitudinally extending edges of the first leg 2b. In particular, the first leg 2b includes a concave surface facing the second leg 3b. In another embodiment, the first leg 2c can include two laterally spaced-apart and longitudinally extending portions thereof, as shown in FIG. 7. In this case, the second leg 3c is located intermediate the two portions of the first leg, the two portions of the first leg 2c being flat and co-planar with each other. The second leg 3c can also be flat and lie in a plane which is perpendicular to a plane containing the two portions of the first leg, as shown in FIG. 7.

FIGS. 10-13 show end views of inventive clips in their open configuration. FIGS. 10-12 show the relative dimensions of each leg of the clip. The clip shown in FIG. 11 has a smaller "y" dimension than the clip shown in FIG. 10, and the clip shown in FIG. 12 has a smaller "x" dimension than the clip shown in FIG. 11. The clip shown in FIG. 12 with the smaller "x" and "y" dimensions allows the clip to be placed in narrow or tight locations.

FIG. 12 also illustrates how legs of "zig-zag" shape can be mechanically straightened in the martensitic state to reduce the "x" and "y" dimensions -- which not only allows the clip to be used in narrow locations, but also provides additional clamping forces in the longitudinal direction when the clip is heated to transform the shape memory alloy into its austenitic state. That is, when the clip shown in FIG. 12 transforms to austenite to its "zig-zag" shape, the bends formed in each leg of the clip not only move toward each other in a transverse direction extending perpendicular to and through the legs, but also move toward each other in a longitudinal direction which is

parallel to the legs when the clip is in its closed configuration. This provides clamping forces in the transverse direction and in the longitudinal direction.

FIG. 13 shows a clip according to the invention which is ready to be applied to a suitable site. FIG. 14 shows a clip after it has been applied to a site and undergone a transformation to the austenitic state.

As pointed out above, it may be desirable to provide a clamping action in the longitudinal and transverse directions. This can be accomplished by providing the legs of the clip with a "zig-zag" shape. As shown in FIG. 15, each leg can include at least one bend 10 therein. This design will allow the clip to hold the tissue very tightly and to prevent slipping. Further details of the "zig-zag" clip of FIG. 15 are shown in FIGS. 16-19. FIGS. 16 and 17 show the clip in the open configuration. FIG. 18 shows the clip after undergoing a shape memory effect but with the arms separated for clarity of illustration. FIG. 19 shows the clip of FIG. 18 with the legs together in the closed position.

FIGS. 20-22 also show details of a "zig-zag" type clip in accordance with the invention. In particular, FIGS. 20a-c show side, top and end views, respectively, of a clip in its open configuration. FIGS. 21a-b show side and end views, respectively, of the clip in its applied configuration. In its closed configuration, the clip will have the memorized shape shown in FIGS. 22a-c which show top, side and end views, respectively. After application by squeezing down on a vessel or tissue (in the state shown in FIGS. 21a-b), the clip will rapidly undergo a temperature rise to body temperature causing it to change its shape

toward the memorized shape shown in FIGS. 22a-c. This results in about a 10% longitudinal shrinkage of the clip as well as interdigitating teeth or fingers which enhance the tenacious hold of the clip on the tissue and help prevent it from sliding or slipping off. This quality makes the clip a more dependable and secure surgical fastening device.

The present invention also provides a method for making a surgical fastening clip having a shape memory effect. The clip comprises the shape memory alloy described earlier, and the method comprises a step (i) of providing a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state, the alloy being deformable in its martensitic state from a first configuration to a second configuration and recovering to the first configuration when heated to transform the alloy to its austenitic state. A step (ii) is performed by forming the alloy into a clip having a substantially U-shaped configuration with two spaced-apart opposed legs extending in a longitudinal direction. A step (iii) is then performed by deforming the clip such that the opposing legs are squeezed together in a closed configuration. A step (iv) is then performed by heating the clip in the closed configuration such that the alloy transforms to its austenitic state. This is the step in which the memory of the clip is set with the clip in the closed configuration. A step (v) is then performed by cooling the clip such that the alloy transforms to its martensitic state. Then, a step (vi) is performed by deforming the clip such that the legs are moved away from each other from the closed configuration to an open configuration, the clip being open and capable of

being deformed in its martensitic state so as to apply a first clamping force on an object and so as to apply a second clamping force on the object when the alloy is heated to transform it to its austenitic state, the second clamping force being greater than the first clamping force. In addition, one or more heat-treating steps can also be applied to the clip for the purposes of forming and heat-treating the clip.

Step (iii) can further include forming at least one projection on at least one of the legs such that when the clip is in its closed configuration the projection extends through a plane extending between the legs. Alternatively, step (iii) can further include forming a plurality of projections on each of the legs such that when the clip is in its closed configuration the projections inter-engage. In order to provide clamping forces in the longitudinal and transverse directions, step (iii) includes forming each of the legs with at least one bend extending perpendicular to the longitudinal direction, and step (vi) further includes straightening each of the legs such that the legs are elongated in the longitudinal direction. In this case, when the alloy is deformed into its closed configuration and then is heated to transform the alloy to its austenitic state, the legs will attempt to resume to the configuration formed by step (iii). Also, step (iii) can further include forming each of the legs in a "zig-zag" pattern, and step (vi) can further include elongating each of the legs to at least partially remove the "zig-zag" pattern.

The invention also provides a method of in vitro clamping of living tissue, such as a vessel or passageway in a human or animal, to stop bleeding or to connect the tissues together. In particular, the

clamping method includes a step (i) of placing opposing legs of a generally U-shaped surgical fastening clip which is in an open configuration around a site of living tissue. The clip comprises a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state. The clip is deformable in its martensitic state from a first configuration to a second configuration and recovers to the first configuration when heated to transform the alloy to its austenitic state. The clip is open and capable of being deformed in its martensitic state so as to apply a first clamping force on an object and so as to apply a second clamping force on the object when the alloy is heated to transform it to its austenitic state, the second clamping force being greater than the first clamping force. The method includes a step (ii) of pressing the legs together to the closed configuration so as to apply the first force to the site. The method includes a step (iii) of heating the clip such that the alloy transforms to its austenitic state and the legs are urged together due to the shape memory effect of the shape memory alloy so as to apply the second force to the site.

The step (ii) is preferably performed at ambient temperature such as in the range of 20 to 25°C. The clip preferably undergoes the shape memory effect by heating in step (iii) to a temperature of less than 37°C, such as a temperature of about 30 to 35°C. Step (ii) can be performed with surgical pliers, the pliers having a pair of pivoted jaws which press the legs of the clip together. Electrical current could also be applied to cause the temperature change of the clip. The method can also include a step (iv) of moving the legs closer together in response to shrinkage of the

site which would otherwise cause the clip to become loosened, step (iv) being accomplished due to a self-biasing force urging the legs together as a result of the shape memory effect.

According to a further feature of the invention, the legs can have a first length in a longitudinal direction with at least one bend in each of the legs when the alloy is in its austenitic state, the legs having a second length in a longitudinal direction without a bend therein when the alloy is in its martensitic state such that the second length is greater than the first length. In this case, step (ii) results in the legs being pressed together without the bend in each of the legs, and step (iii) results in shrinkage of the legs in a longitudinal direction such that the bend in one of the legs presses in a longitudinal direction against the bend in the other one of the legs. The shortening of the clip in the longitudinal direction helps to prevent flattening or thinning of the tissue, thereby making it more readily gripped by the clip or the teeth on the clip.

One form of the Nitinol ligating clip may be manufactured by imparting the memory of the wire in a helix by winding it into that shape and treating it in that shape by raising its temperature to 450°C for about one minute. A 50.6% nickel to 49.4% titanium alloy will have an appropriate transition temperature of 30-32°C after some cold working. After cooling, the wire can be straightened and wound into spools which can then be fed through existing clip making machinery. The clips can have shapes similar or identical to existing clips. These clips can be applied at room temperature with application tools similar to those used with existing clips. During application, the throat or apex of the clip will be plastically deformed

beyond the point at which shape memory can be recovered.

Very soon after application, the arms of the clip will rise to body temperature and will attempt to return to the curve in their memory. This will make them do work by exerting force as they move toward each other. If the clipped tissue becomes thinner as time passes, the arms will continue to do work as they exert force to close toward each other.

The clip can be made to have a two-dimensional memory shape in the arms. One shape is the curve of the helix diameter and the second is a "zig-zag" shape at a 90° angle to the other shape. This can be done by putting a back and forth "zig-zag" shape in the wire as it is wound on the mandrel for the curve shape. The wire is straightened after the memory is set, and the clips are made in the same way. After application, when the arms go through the transition temperature, they will do work by moving toward each other, and they will also move into the other dimensional "zig-zag" shape, thereby enhancing their grip on the tissue and improving clip security.

The first described clip can be made from a continuous roll of the alloy wire that has the curve memory. It can be fed down an instrument designed to cut a length of wire, form it into a ligating clip and then apply it. This would allow the clips to be applied one after another as fast as the actuating mechanism could be operated.

A surgical staple similar to the above ligating clip can be made in an identical manner. Staples are useful for fastening body tissues together or fastening a man-made material to body tissues. The

staple has a pre-application shape similar to the clips and is applied in a similar manner. After application, the arms of the staple will cross, thereby securely locking the tissues together. Nitinol staples will be easier to apply because the shape memory recovery will do the work, and they will not need the complicated wire-deforming devices that present staples require.

Still another similar device can be made using similar manufacturing techniques and utilizing the same principles. The tying of surgical knots during laparoscopic surgery is difficult, laborious and time-consuming. A smaller, stronger clip made and applied in a similar manner to sutures to fasten them instead of tying knots will greatly speed up laparoscopic surgical procedure.

According to another feature of the invention, the clip can be made in a way which allows the legs to do work at individual points along the legs when the alloy transforms to its austenitic state, regardless of whether a connecting portion between the legs possesses a shape memory effect. In particular, depending on how the clip is made, it is possible that the clip may not be recoverable from an open configuration to the closed configuration due to excessive plastic deformation of the connecting portion interconnecting the two legs. For instance, if the clip is V-shaped (as shown in FIG. 23) and the clip has been previously heat-treated to memorize the closed configuration, when the legs are spread apart to form an open clip and/or are closed to clamp an object, the extent of plastic deformation at connecting portion 10 may destroy the ability of the connecting portion to move the arms to the fully closed configuration when the alloy transforms to its austenitic state. This problem can be avoided by making the clip from a wire

which has been previously pre-set in a memorized non-linear shape or by heat-treating the legs after the clip is formed.

The clip can be formed out of a wire which has been pre-set in a memorized non-linear shape such as a helix. This memorized shape can be obtained by coiling the wire around a mandrel, heating the coiled wire to transform the alloy into its austenitic state and cooling the coiled wire to transform the alloy into its martensitic state. The wire can then be straightened, wound on a spool and fed through conventional clip-making machinery. The clips formed according to this process possess a unique and highly advantageous property in that the legs, if unrestrained, will assume the non-linear shape when the alloy transforms into its austenitic state. The legs will exhibit this effect whether or not the connecting portion between the legs loses the shape memory effect when the legs are squeezed together. For an added clamping effect, the wire is formed with undulations or "zig-zags" prior to being heat-treated, and the wire is straightened after the heat treatment to remove the undulations or "zig-zags". In use, the legs of the clip will shrink to provide added clamping when the alloy transforms into the austenitic state.

Another way to avoid the loss of the shape memory effect when either the clip is formed and/or is applied to a site is by forming the clip such that the connecting portion is Y-shaped, as shown in FIG. 24. In this case, the angle between legs 2,3 is small enough to avoid loss of the shape memory effect due to plastic deformation of connecting portion 10a when legs 2,3 are spread apart to form an open clip and/or are closed during use of the clip to clamp an object. It should be noted that the clip shown in FIG. 24 can be

heat-treated in its closed configuration or made from wire which has been pre-set in a memorized non-linear shape and subsequently formed into the shape shown in FIG. 24.

Another way to avoid the problem of loss or lack of the shape memory effect in the connecting portion is by differentially heat-treating the arms of the clip. For instance, as shown in FIG. 25, connecting portion 10a of the clip can be held in heat sink 11, and the free ends of arms 2,3 can be bent into a desired shape, heated to transform the free ends into the austenitic state and cooled to transform the free ends into the martensitic state. For instance, an electrical current can be passed through the free ends of the arm to heat them to about 700°C. Subsequently, the free ends can be straightened into the shape shown on the left side of FIG. 24. When the clip is in use, the arms are squeezed together around an object. When the arms heat to transform the alloy into the austenitic state, the free ends of the arms will attempt to return to the shape shown in FIG. 25 and provide additional clamping.

The clip in accordance with the invention can have a memorized configuration which causes the arms to move past each other. For instance, as shown in FIG. 26, clip 12 can be a staple which is inserted into two pieces of tissue 13,14. As clip 12 warms to body temperature and transforms to the austenitic state, the ends of the arms move together and cross while pulling tissues 13,14 together. This feature of the invention can also be used to fasten sutures, as shown in FIG. 27. For instance, clip 15 can be used to fasten suture 16 in tissues 17,18. Thus, the difficult, laborious and time-consuming tying of surgical knots such as

during laparoscopic surgery can be obviated by using small clips in accordance with the invention.

According to another aspect of the invention, a tool is provided for making and applying surgical fastening clips made of a shape memory alloy. For instance, as shown in FIG. 28, tool 19 includes housing 20 and support means 21 for supporting a member to be formed into a surgical fastening clip. Housing 20 includes feeding and forming means 22 (hereinafter "forming means 22") for feeding the member and forming a surgical *fastening clip. The member preferably* comprises wire 26 of a shape memory alloy having an austenitic transition temperature in the range of 30 to 35°C, preferably 30 to 32°C. The wire can be stored on a spool which is supported by the support means 21. Cutting means 23 cuts a section of the wire into an appropriate length, and forming means 22 forms the cut section of the wire into a desired shape of the fastening clip. Tool 19 includes applying means 25 which can be used to position the clip around a site and bend the clip so as to clamp the site. Tool 19 includes transport means 24 for moving the formed clip to a position adjacent the free ends of the applying means 25.

An alternative arrangement of a tool for forming clips and applying them is shown in FIG. 29. In this case, tool 19a includes housing 20a wherein support means 21 and forming means 22a are located. Again, the member can be a wire of a Ni-Ti based shape memory alloy wound on a spool supported in support means 21. Forming means 22a includes a shaping member having the shape of the desired clip. Wire 26 is fed from the spool and into the shaping member, after which cutting means 23 cuts wire 26. Transport means 24a holds the clip in the desired shape and transports it

to the free ends of the applying means 25. The arms of the applying means 25 can be squeezed together to plastically deform legs 2,3 of the clip around a site.

Although two forms of a tool have been described with reference to FIGS. 28 and 29, many other variations of such a tool are possible. The essential features of the tool are that a member is supported in a support means, the member is fed by feeding means to a forming means for forming the member into a desired shape of a clip, and applying means plastically deforms the clip around a site such that arms 2,3 clamp the site.

While the invention has been described with reference to the foregoing embodiments, various changes and modifications can be made thereto which fall within the scope of the appended claims.

What is Claimed is:

1. A surgical fastening clip, comprising:

a substantially U-shaped member of a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state;

the clip being deformable in its martensitic state from a first configuration to a second configuration and recovering to the first configuration when heated to transform the alloy to its austenitic state; and

the clip being open and capable of being deformed in its martensitic state so as to apply a first clamping force on an object and so as to apply a second clamping force on the object when the alloy is heated to transform it to its austenitic state, the second clamping force being greater than the first clamping force.

2. The clip of claim 1, wherein the clip includes first and second opposing legs joined together at one end thereof, the legs having free ends at the other end thereof.

3. The clip of claim 1, wherein the alloy transforms to its austenitic state at a temperature in the range of about 30 to 35°C.

4. The clip of claim 1, wherein the alloy transforms to its austenitic state at a temperature below 37°C.

5. The clip of claim 2, wherein each of the legs is substantially V-shaped in lateral cross-section.

6. The clip of claim 1, wherein each of the legs includes a pair of longitudinally extending sections, the sections being joined together at the lower longitudinally extending edges thereof and being laterally separated from each other at the upper longitudinally extending edges thereof.

7. The clip of claim 1, wherein the clip comprises a single flat strip of material which has been deformed into the U-shaped member.

8. The clip of claim 7, wherein the flat strip of material includes longitudinally spaced-apart end sections forming the legs and a center section therebetween, the center section having laterally spaced-apart edges which are closer together than the laterally spaced-apart edges of each of the end sections.

9. The clip of claim 8, wherein each of the end sections includes a longitudinally extending V-shaped bend.

10. The clip of claim 9, wherein the V-shaped bends fit together in a complementary manner when the clip is in its closed configuration such that the upper surfaces of one of the V-shaped bends face lower surfaces of another one of the V-shaped bends.

11. The clip of claim 9, wherein the V-shaped bends fit together in a complementary manner such that only one surface forming one of the V-shaped

bends faces one surface forming the other V-shaped bend.

12. The clip of claim 8, wherein one of the end sections includes a longitudinally extending V-shaped bend.

13. The clip of claim 2, wherein the first leg is substantially V-shaped in lateral cross-section.

14. The clip of claim 13, wherein the second leg is substantially rectilinear in lateral cross-section.

15. The clip of claim 14, wherein the second leg includes a longitudinally extending edge thereof located intermediate opposing longitudinally extending edges of the first leg.

16. The clip of claim 15, wherein the first leg includes a concave surface facing the second leg.

17. The clip of claim 2, wherein the first leg includes two laterally spaced-apart and longitudinally extending portions thereof.

18. The clip of claim 17, wherein the second leg is located intermediate the two portions of the first leg.

19. The clip of claim 17, wherein the two portions of the first leg are flat and co-planar with each other.

20. The clip of claim 17, wherein the second leg is flat and lies in a plane which is perpendicular

to a plane containing the two portions of the first leg.

21. The clip of claim 2, wherein the first and second clamping forces are in a transverse direction which is perpendicular to and extends through the first and second legs.

22. The clip of claim 21, wherein the first and second clamping forces are also in a longitudinal direction which is parallel to the first and second legs when the clip is in its closed configuration.

23. The clip of claim 22, wherein at least one of the first and second legs includes at least one bend perpendicular to the longitudinal direction which is formed when the clip is heated and transforms to its austenitic shape.

24. The clip of claim 22, wherein the first leg has a first length in the longitudinal direction between the ends thereof when the alloy is in its martensitic state and the first leg has a second length in the longitudinal direction between the ends thereof when the alloy is heated and transforms to its austenitic state, the second length being shorter than the first length.

25. The clip of claim 24, wherein the first leg includes a first projection thereon and the second leg includes a second projection thereon, the first and second projections moving toward each other in the longitudinal direction when the alloy transforms to its austenitic state.

26. A method of making a surgical fastening clip having a shape memory effect, comprising:

(i) providing a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state, the alloy being deformable in its martensitic state from a first configuration to a second configuration and recovering to the first configuration when heated to transform the alloy to its austenitic state;

(ii) forming the alloy into a clip having a substantially U-shaped configuration with two spaced-apart opposing legs extending in a longitudinal direction;

(iii) deforming the clip such that the opposing legs are squeezed together in a closed configuration;

(iv) heating the clip in the closed configuration such that the alloy transforms to its austenitic state;

(v) cooling the clip such that the alloy transforms to its martensitic state; and

(vi) deforming the clip such that the legs are moved away from each other from said closed configuration to an open configuration, the clip being open and capable of being deformed in its martensitic state so as to apply a first clamping force on an object and so as to apply a second clamping force on the object when the alloy is heated to transform to its austenitic state, the second clamping force being greater than the first clamping force.

27. The method of claim 26, wherein step (iii) further comprises forming at least one projection on at least one of the legs such that when the clip is in its closed configuration the projection extends through a plane extending between the legs.

28. The method of claim 26, wherein step (iii) further comprises forming a plurality of projections on each of the legs such that when the clip is in its closed configuration the projections inter-engage.

29. The method of claim 26, wherein step (iii) further comprises forming each of the legs with at least one bend along a length thereof and step (vi) further comprises straightening each of the legs to at least partially remove the bend such that the legs are elongated in said longitudinal direction.

30. The method of claim 26, wherein step (iii) further comprises forming each of the legs in a zig-zag pattern and step (vi) further comprises elongating each of the legs to at least partially remove the zig-zag pattern.

31. A method of in vitro clamping of living tissue such as a vessel or passageway in a human or animal, comprising:

(i) placing opposed legs of a generally U-shaped surgical fastening clip which is in an open configuration around a site of living tissue, the clip comprising a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state;

the clip being deformable in its martensitic state from a first configuration to a second configuration and recovering to the first configuration when heated to transform the alloy to its austenitic state;

the clip being open and capable of being deformed in its martensitic state so as to apply a

first clamping force on an object and so as to apply a second clamping force on the object when the alloy is heated to transform it to its austenitic state, the second clamping force being greater than the first clamping force;

(ii) pressing the legs together to the closed configuration so as to apply said first force to the site; and

(iii) heating the clip such that the alloy transforms to its austenitic state and the legs are urged together due to the shape memory effect of the shape memory alloy so as to apply said second force to the site.

32. The method of claim 31, wherein step (ii) is performed at ambient temperature.

33. The method of claim 31, wherein step (ii) is performed at a temperature in the range of 20 to 25°C.

34. The method of claim 31, wherein the clip undergoes the shape memory effect by heating in step (iii) to a temperature of less than 37°C.

35. The method of claim 31, wherein the clip undergoes the shape memory effect by heating in step (iii) to a temperature of about 30 to 35°C.

36. The method of claim 31, wherein step (ii) is performed with surgical pliers, the pliers having a pair of pivoted jaws which press the legs of the clip together.

37. The method of claim 31, further comprising a step (iv) of moving the legs closer together in response to shrinkage of the site which

would otherwise cause the clip to become loosened, step (iv) being accomplished due to a self-biasing force urging the legs together as a result of the shape memory effect.

38. The method of claim 31, wherein the legs have a first length in a longitudinal direction with at least one bend in each of the legs when the alloy is in its austenitic state, the legs having a second length in the longitudinal direction without a bend therein when the alloy is in its martensitic state with the second length being greater than the first length, step (ii) resulting in the legs being pressed together without the bend in each of the legs and step (iii) resulting in shrinkage of the legs in the longitudinal direction such that the bend in one of the legs presses in the longitudinal direction against the bend in the other one of the legs.

39. A surgical fastening clip, comprising:

a member having first and second legs interconnected at one end thereof, the member being of a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state;

the legs of the clip being deformable when the alloy is in its martensitic state from a memorized configuration wherein each of the legs is non-linear to a heat-unstable configuration wherein each of the legs is straight, the legs recovering to the memorized configuration when the alloy is heated to transform the alloy to its austenitic state;

the clip having an open configuration wherein the legs are spaced apart and the clip being deformable in its martensitic state to a closed configuration

wherein the legs are closer together so as to apply a first clamping force on an object, the legs applying a second clamping force on the object when the alloy is heated to transform it to its austenitic state wherein the legs recover to the memorized configuration, the second clamping force being greater than the first clamping force.

40. The clip of claim 39, wherein the legs are straight when the clip is in its martensitic state and the legs have an undulating shape when the alloy is heated and transforms to its austenitic state.

41. The clip of claim 39, wherein the legs are straight when the clip is in its martensitic state and the legs have a curved shape when the alloy is heated and transforms to its austenitic state.

42. The clip of claim 39, wherein the legs are straight when the clip is in its martensitic state and free ends of the legs move past each other when the alloy is heated and transforms to its austenitic state.

43. The clip of claim 39, wherein the legs are straight when the clip is in its martensitic state, the legs bending arcuately around the object and free ends of the legs move closer together when the alloy is heated and transforms to its austenitic state.

44. The clip of claim 39, wherein the member comprises a piece of wire having a non-circular cross-section and the alloy comprises a Ni-Ti based shape memory alloy having an austenitic transformation temperature in the range of 30 to 35°C.

45. The clip of claim 44, wherein the cross-section includes a flat portion and at least one curved portion.

46. The clip of claim 39, wherein the clip includes a connecting portion interconnecting the legs, the connecting portion being V-shaped, U-shaped or Y-shaped and the clip comprising a single piece of wire.

47. The clip of claim 46, wherein the connecting portion exhibits no shape memory effect when the clip is deformed from the open configuration into the closed configuration and the alloy is heated into its austenitic state, the shape memory effect being destroyed due to excessive plastic deformation of the connecting portion when the clip is deformed from the open configuration into the closed configuration.

48. A method of making a surgical fastening clip having a shape memory effect, comprising steps of:

(i) providing an elongated member of a shape memory alloy having a martensite transformation temperature below which the alloy transforms to its martensitic state and an austenite transformation temperature above which the alloy transforms to its austenitic state;

(ii) bending the member into a non-linear configuration;

(iii) heating the member in the non-linear configuration such that the alloy transforms to its austenitic state;

(iv) cooling the member such that the alloy transforms to its martensitic state, the non-linear configuration being retained during the cooling of the member; and

(v) plastically deforming the member into a surgical fastening clip having first and second legs

interconnected at one end thereof by a connecting portion of the clip.

49. The method of claim 48, wherein the member comprises a wire of a Ni-Ti based shape memory alloy having an austenitic transformation temperature in the range of 30 to 35°C.

50. The method of claim 48, wherein the member comprises a wire and step (ii) is performed by helically winding the wire on a mandrel.

51. The method of claim 50, further comprising a step of straightening the wire between steps (iv) and (v).

52. The method of claim 51, wherein after the straightening step, the wire is wound onto a spool and fed through clip-making machinery wherein step (v) is performed.

53. The method of claim 48, wherein the member is heated to at least 400°C for at least one minute during step (iii).

54. The method of claim 48, wherein the connecting portion formed in step (v) is Y-shaped and an angle between the legs is small enough to prevent loss of the shape memory effect in the connecting portion when the legs are squeezed together to close the clip.

55. The method of claim 48, wherein the member comprises a wire and step (ii) is performed by forming undulations in the wire.

56. The method of claim 55, further comprising a step of straightening the wire between steps (iv) and (v).

57. The method of claim 54, further comprising steps of placing the connecting portion in a heat sink, plastically deforming free ends of the legs such that they are bent, heating the free ends of the legs such that the free ends transform to the austenitic state, cooling the free ends such that the free ends transform to the martensitic state and straightening the free ends.

58. A tool for making surgical fastening clips and applying them to an object, comprising:

a housing;

support means for supporting wire in the housing;

feeding means for feeding wire from the support means;

forming means for forming wire fed by the feeding means into a shape of a surgical fastening clip; and

applying means for applying a surgical fastening clip formed by the forming means to an object.

59. The tool of claim 58, further comprising cutting means for cutting a section of wire fed by the feeding means, the forming means forming a section of wire cut by the cutting means into the shape of a surgical fastening clip.

60. The tool of claim 58, further comprising wire supported by the support means.

61. The tool of claim 60, wherein the wire comprises a spool of wire.

62. The tool of claim 58, wherein the wire comprises a Ni-Ti based shape memory alloy which has been heat-treated to have a memorized non-linear configuration and subsequently plastically deformed in its martensitic condition from the non-linear configuration into a second configuration different from the non-linear configuration.

63. The tool of claim 62, wherein the non-linear configuration comprises a helical shape and the second configuration comprises a generally rectilinear shape.

64. The tool of claim 62, wherein the non-linear configuration comprises an undulating wire and the second configuration comprises a wire without undulations.

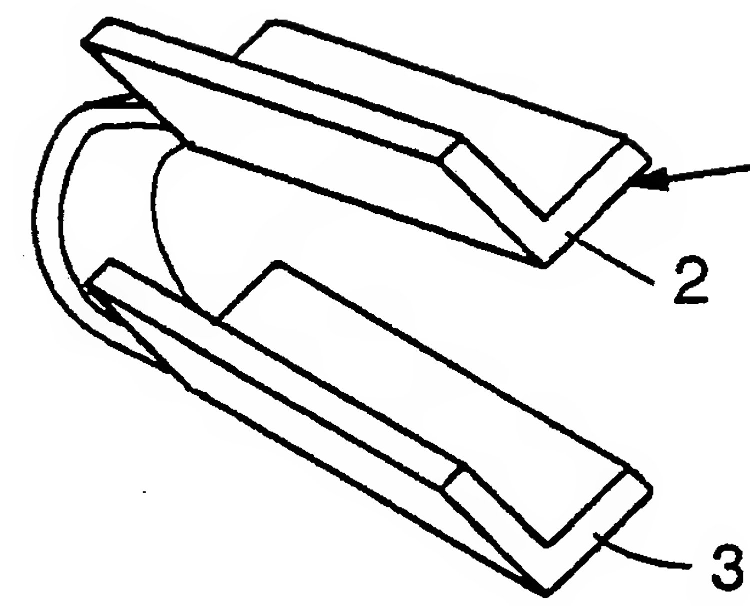


FIG. 1

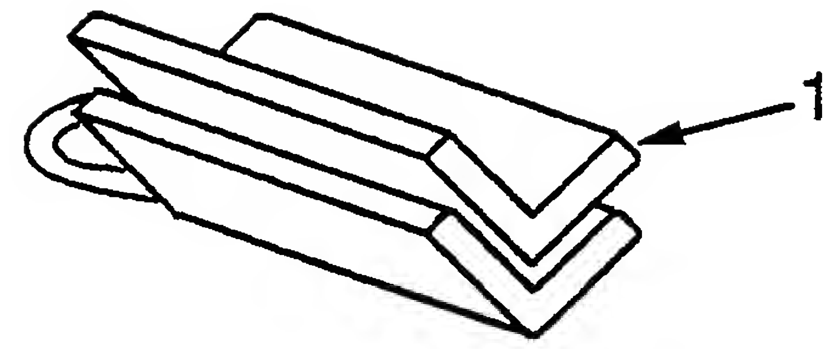


FIG. 2

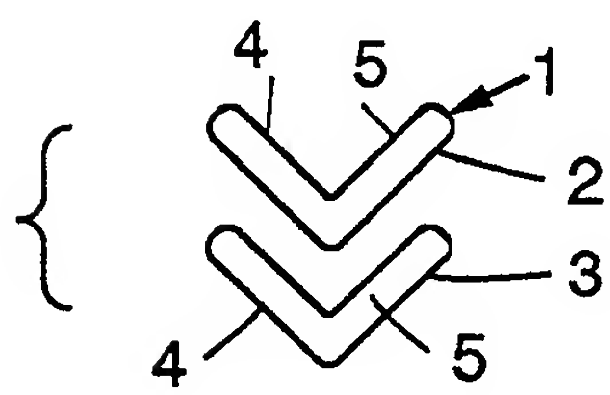


FIG. 3

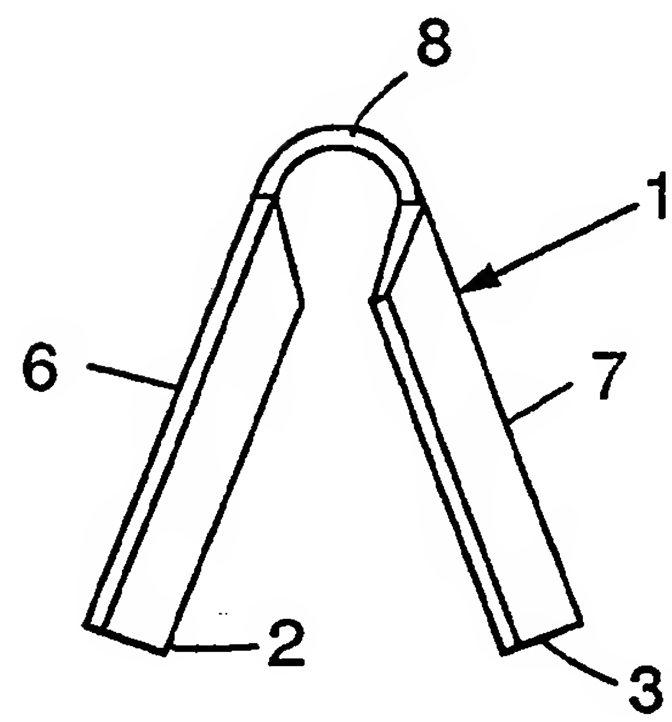


FIG. 4

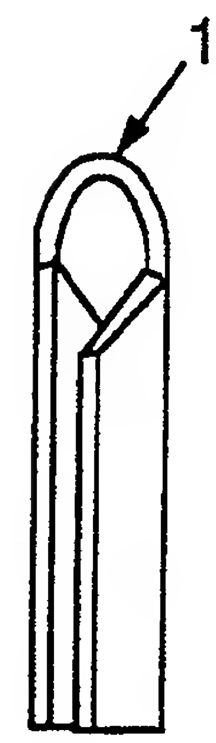


FIG. 5

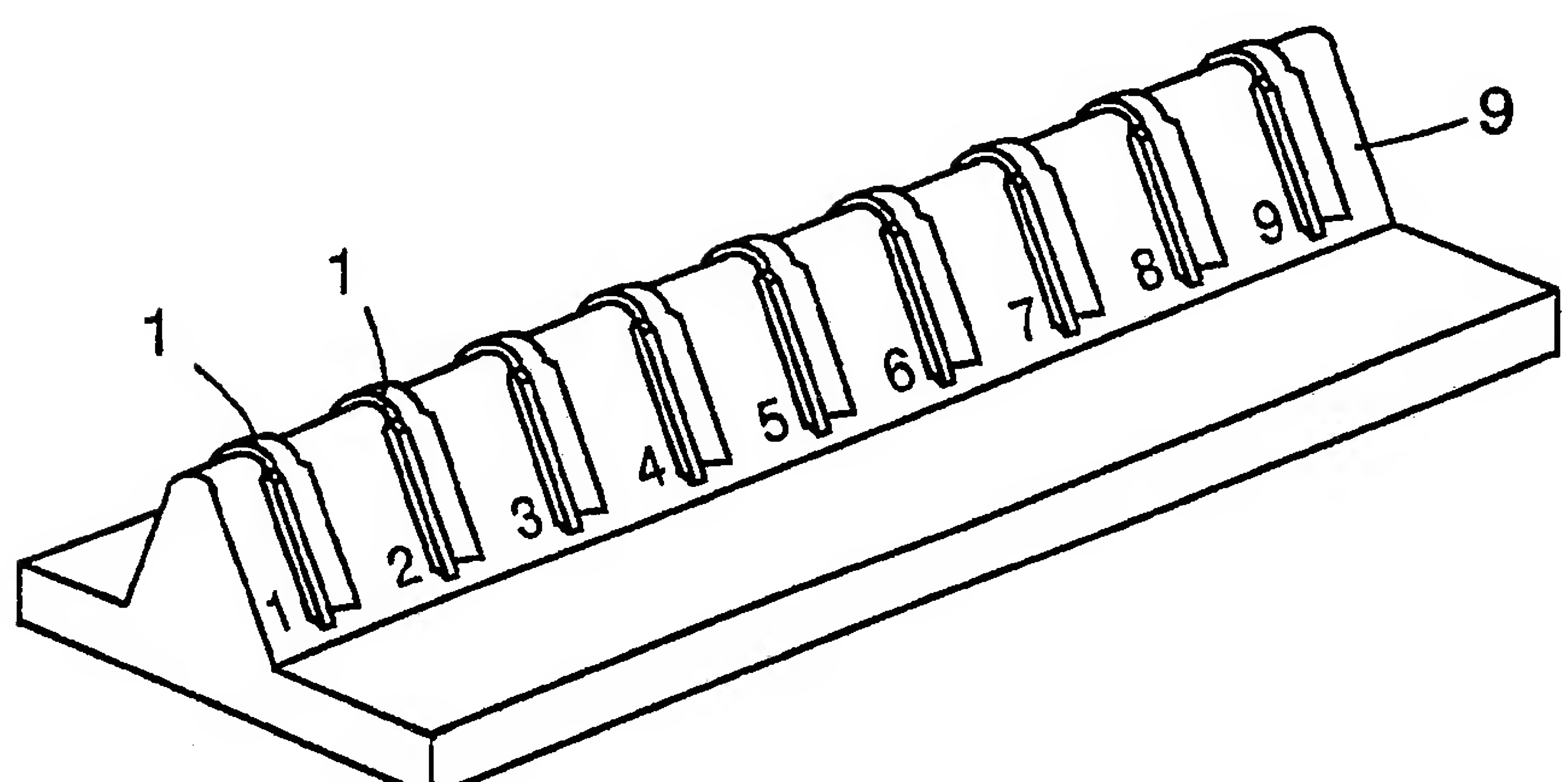


FIG. 6

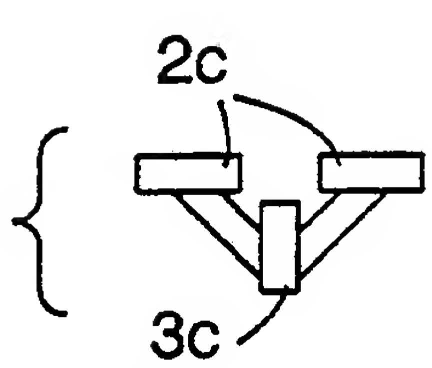


FIG. 7

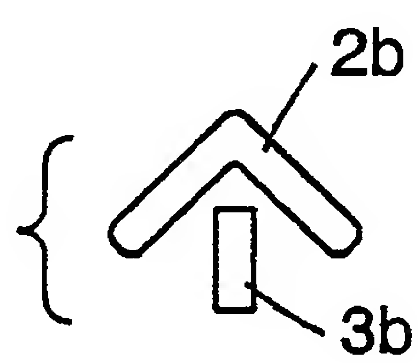


FIG. 8

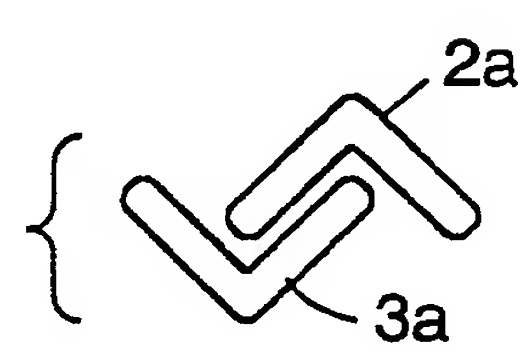


FIG. 9

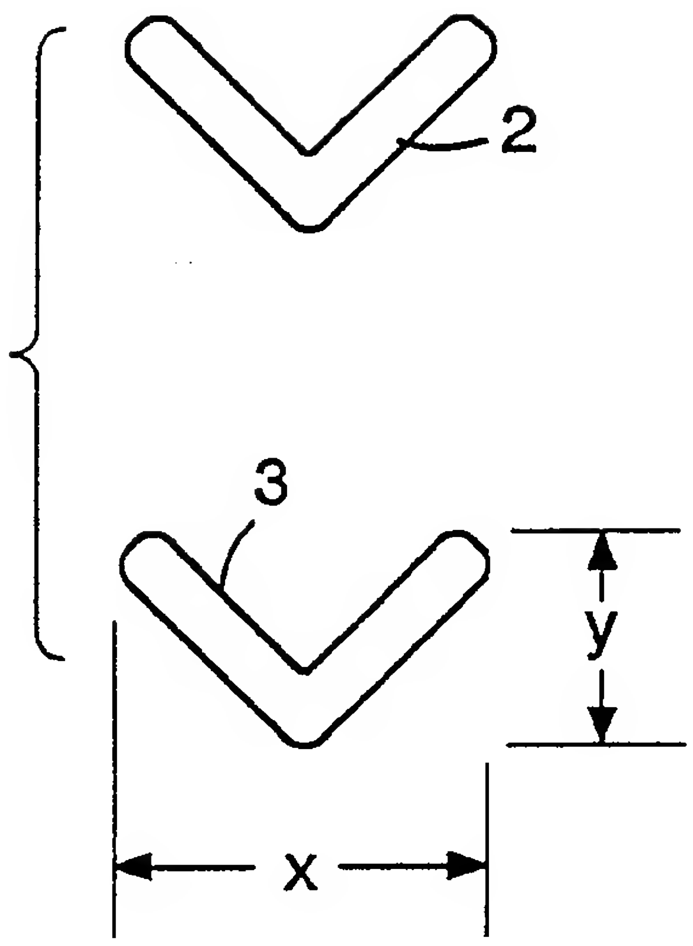


FIG. 10

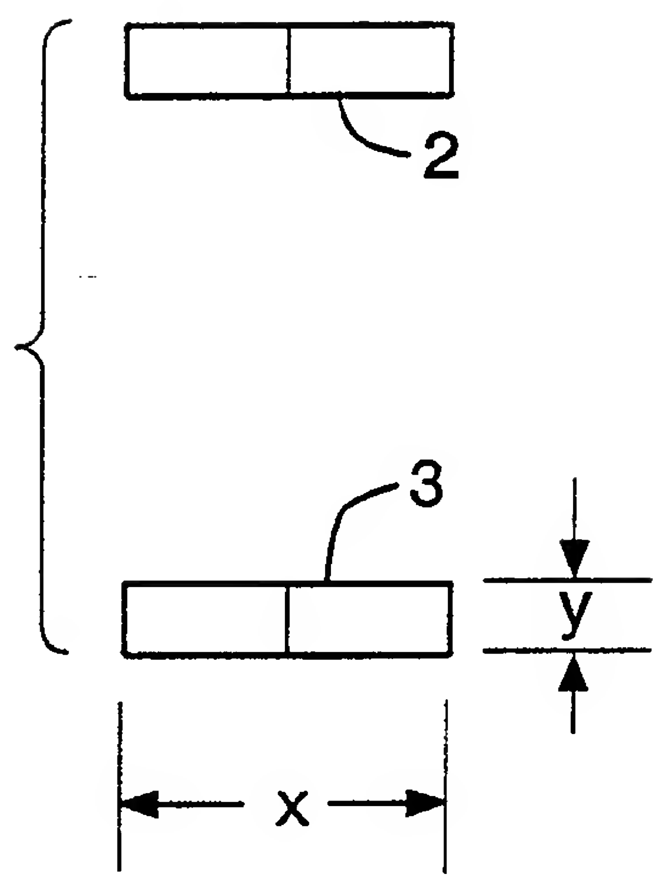


FIG. 11

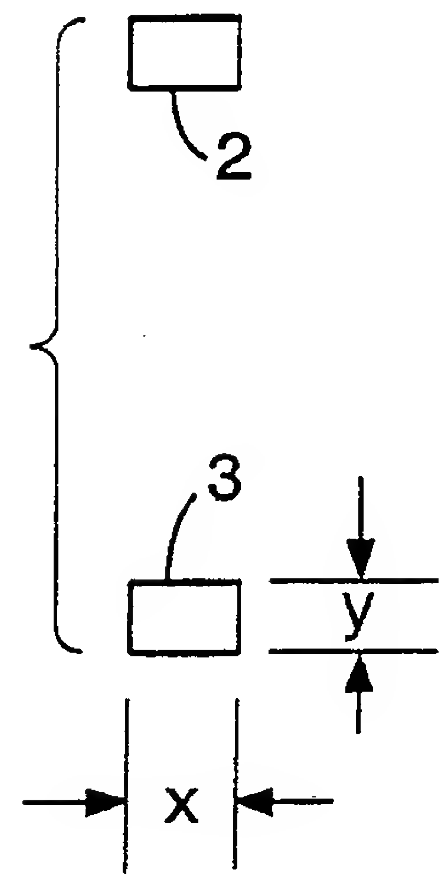


FIG. 12

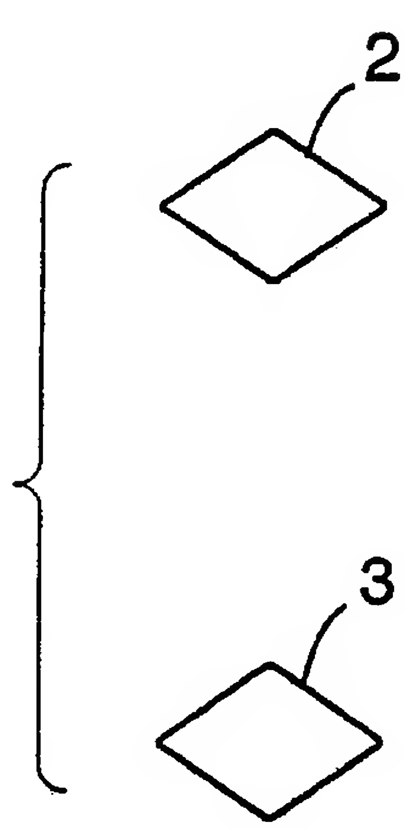


FIG. 13

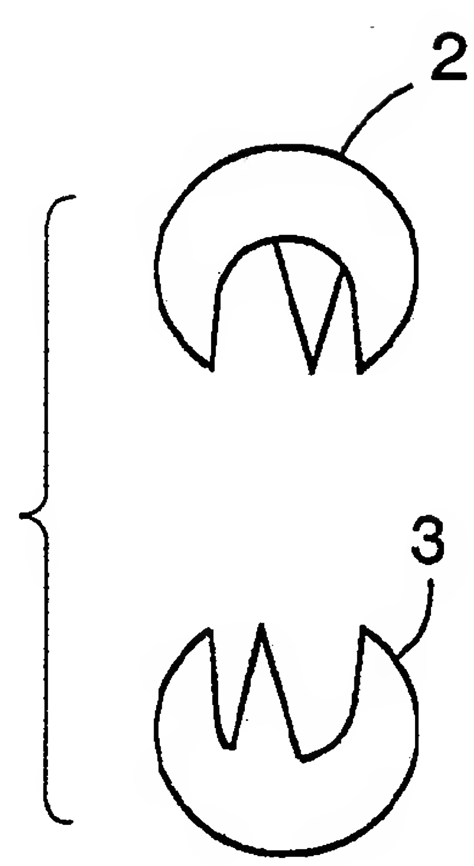


FIG. 14

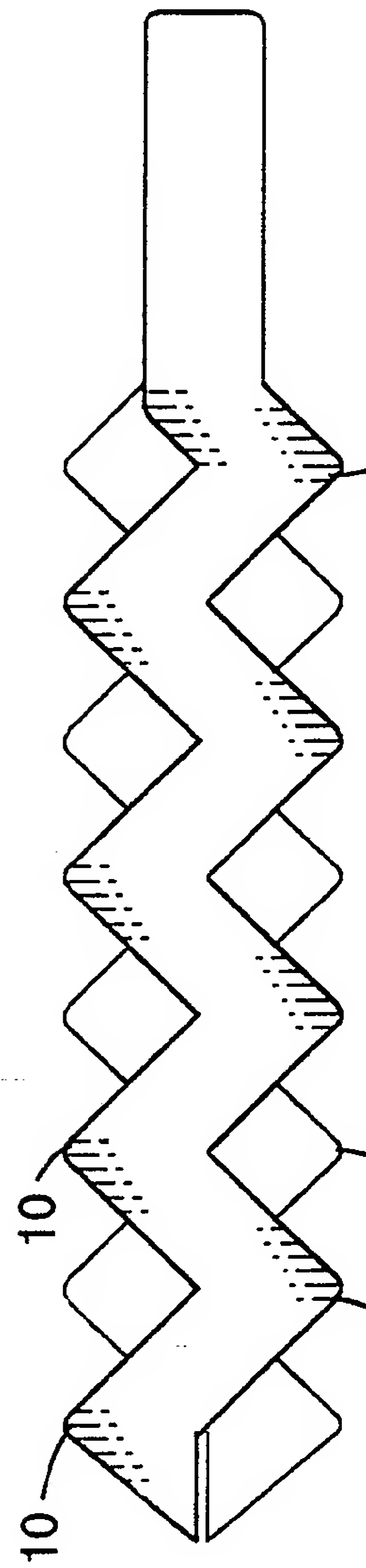


FIG. 15

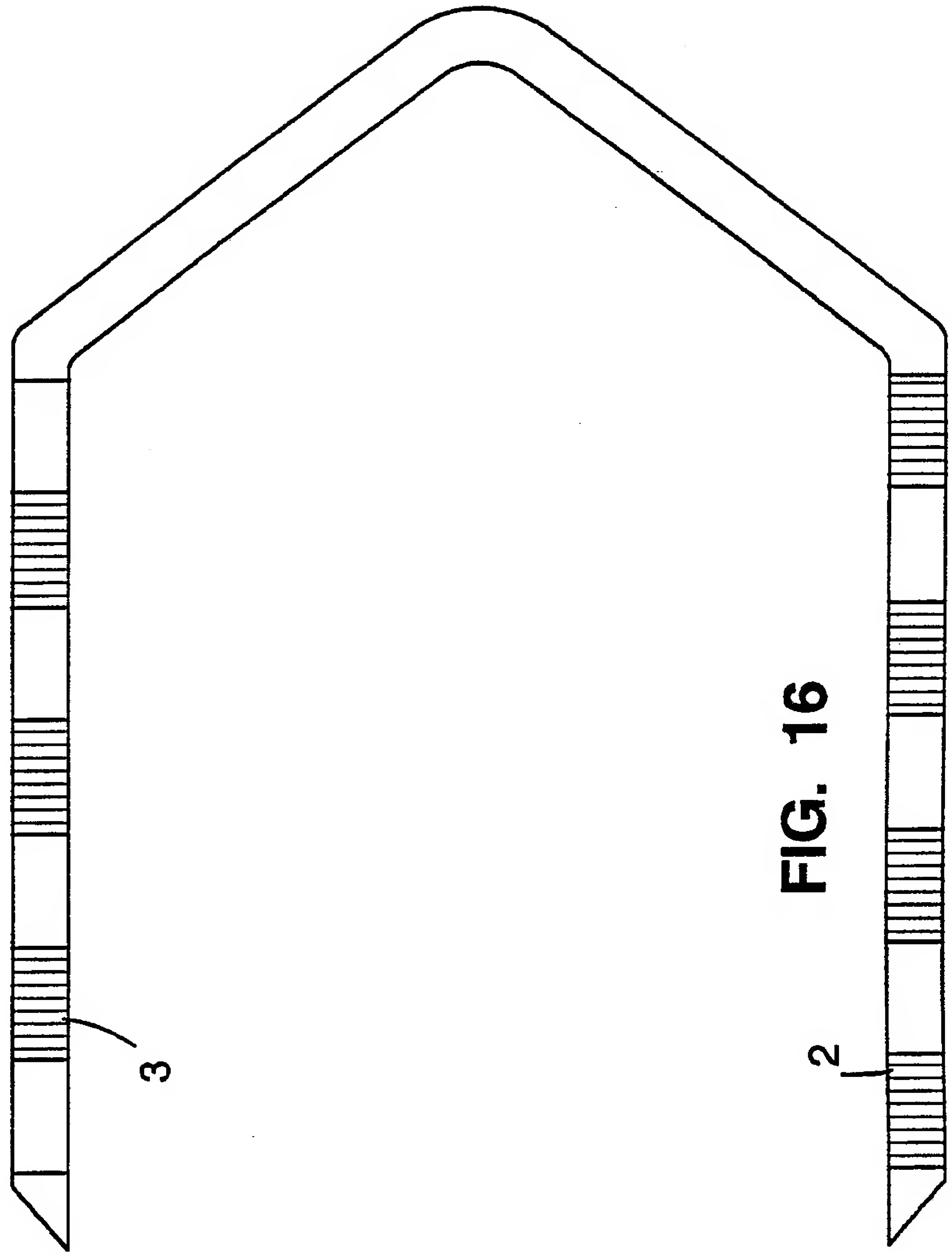


FIG. 16

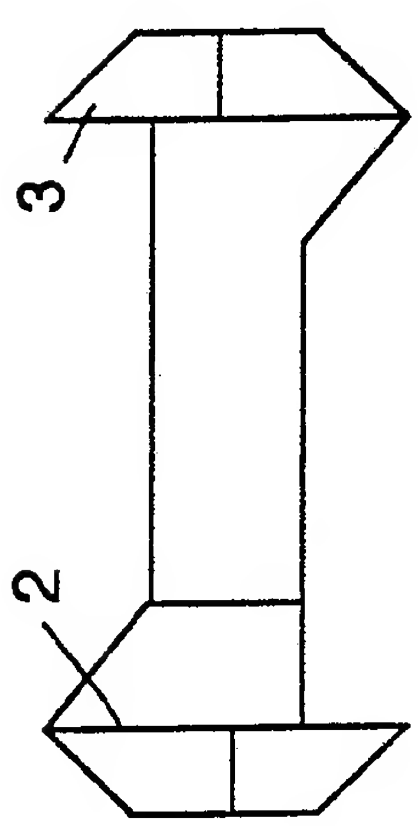


FIG. 17

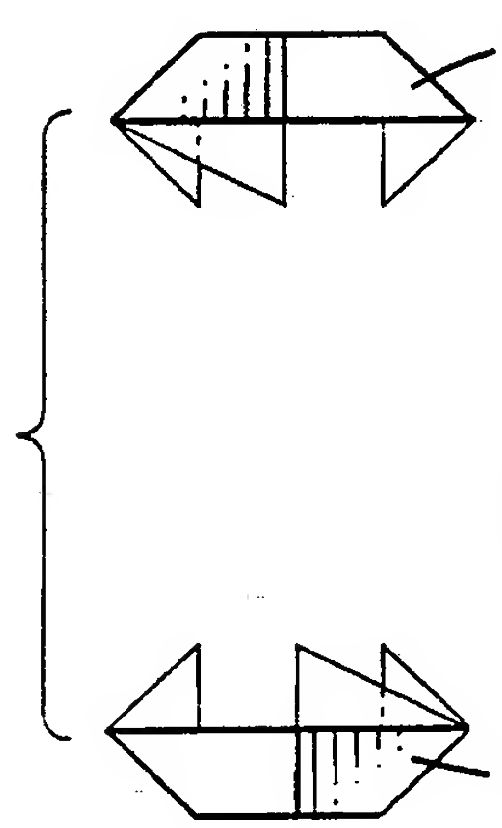


FIG. 18

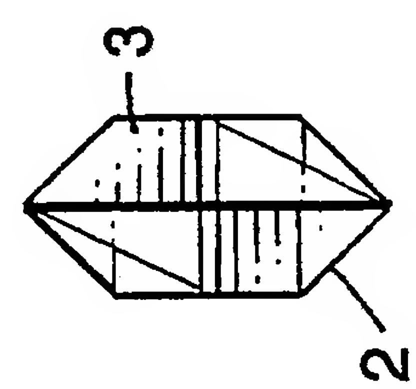


FIG. 19

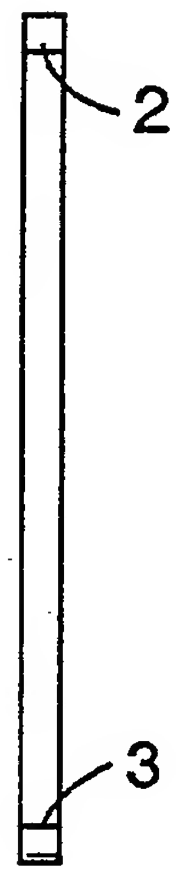


FIG. 20c

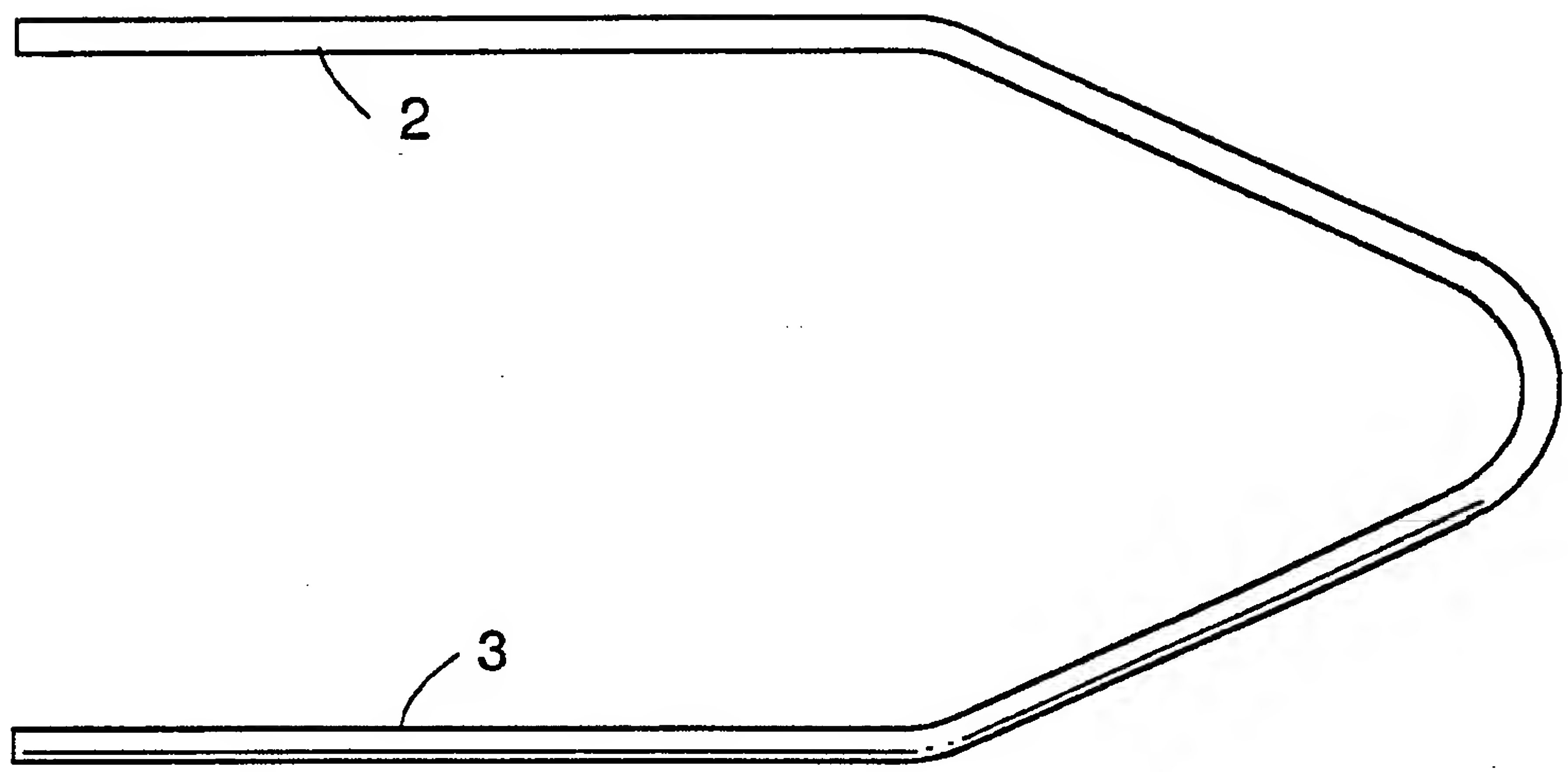


FIG. 20a

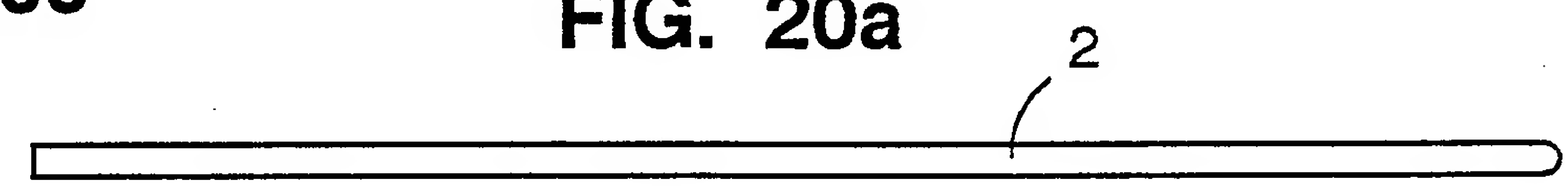


FIG. 20b

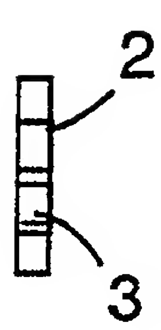


FIG. 21b

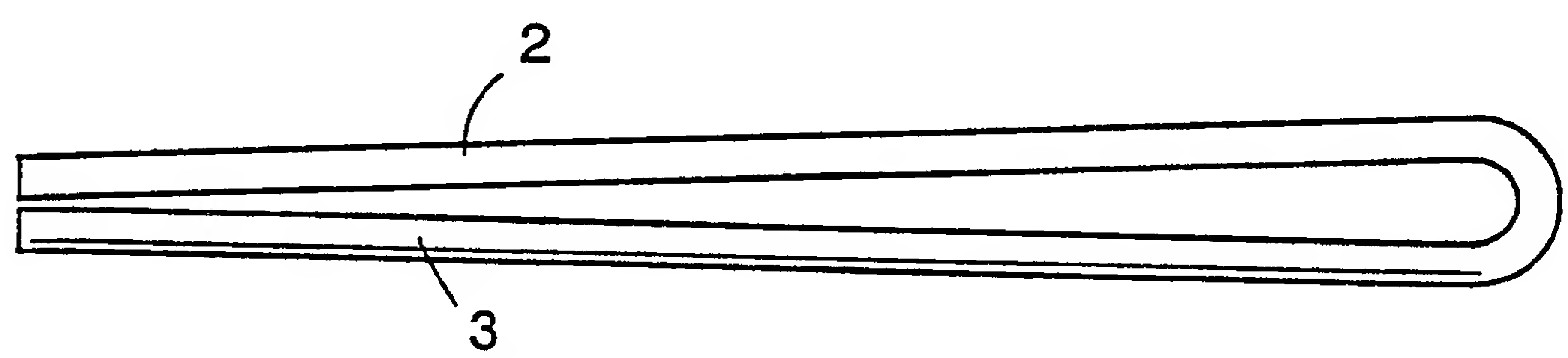


FIG. 21a

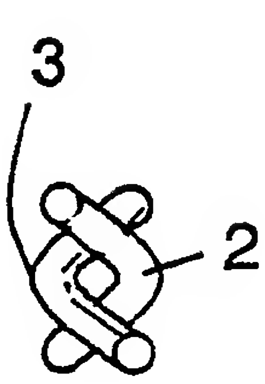


FIG. 22c

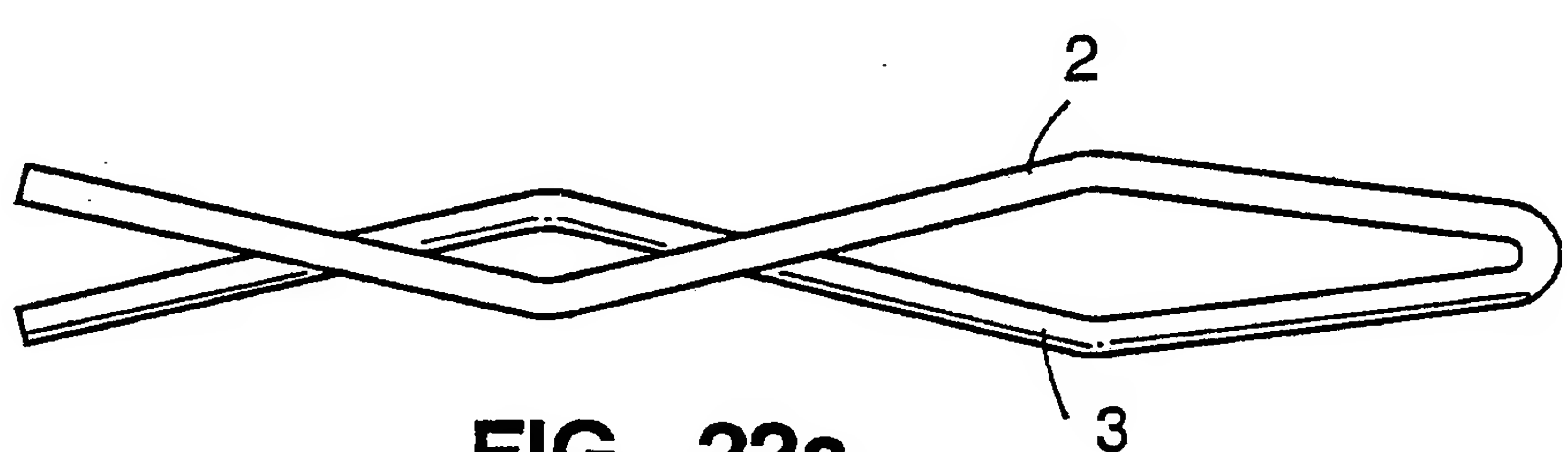


FIG. 22a

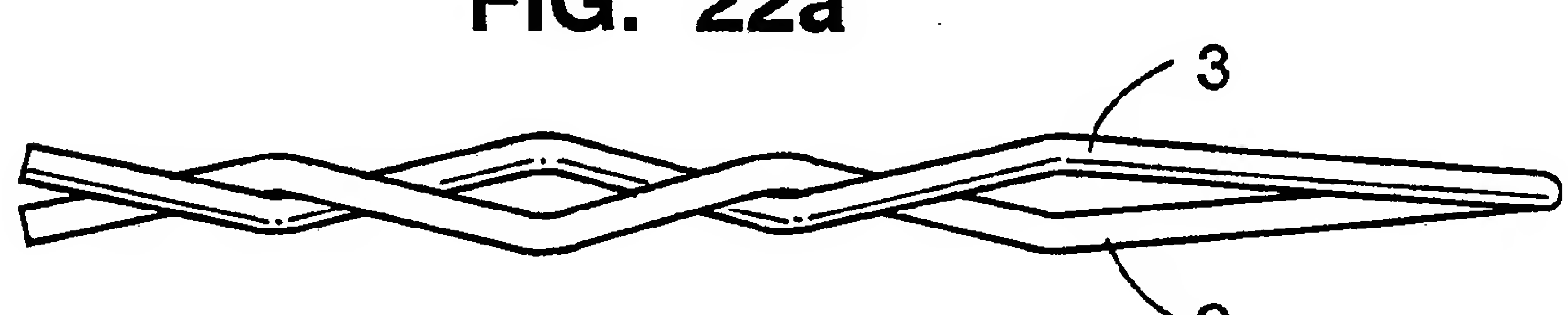


FIG. 22b

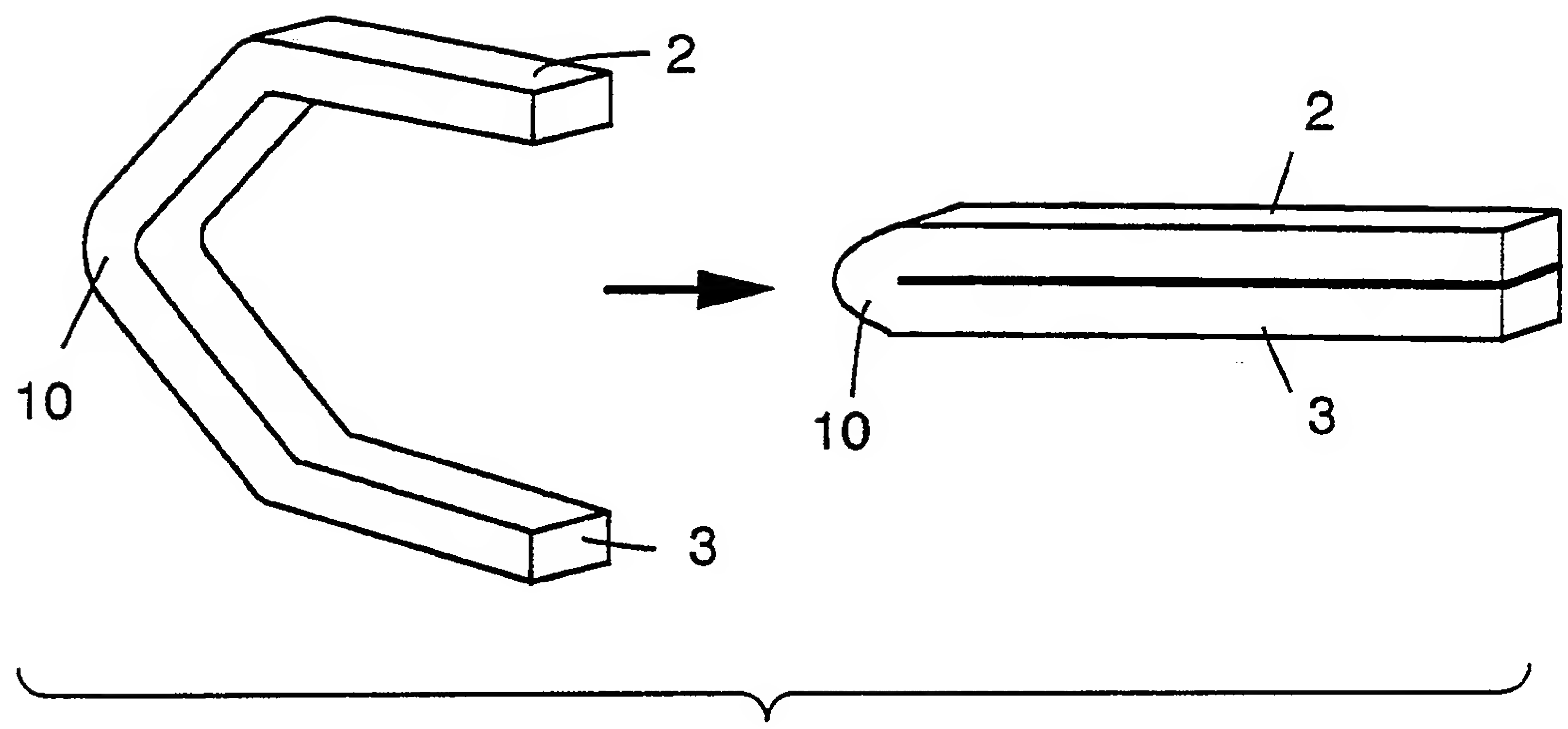


FIG. 23

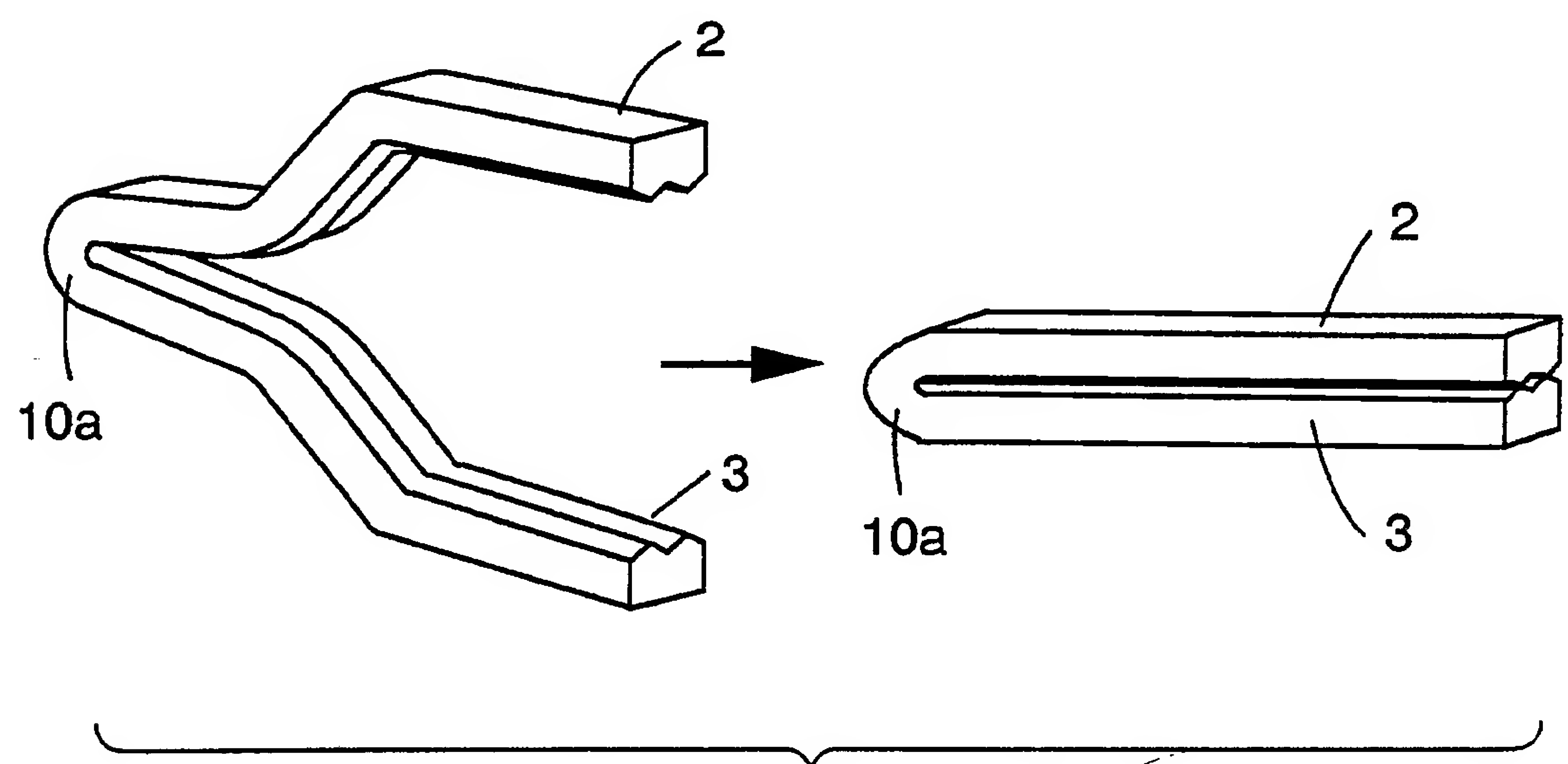


FIG. 24

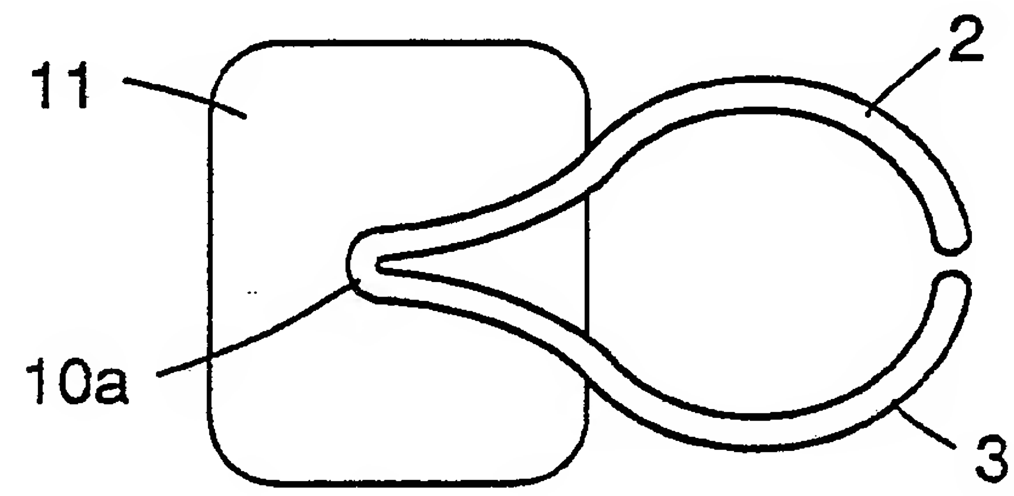


FIG. 25

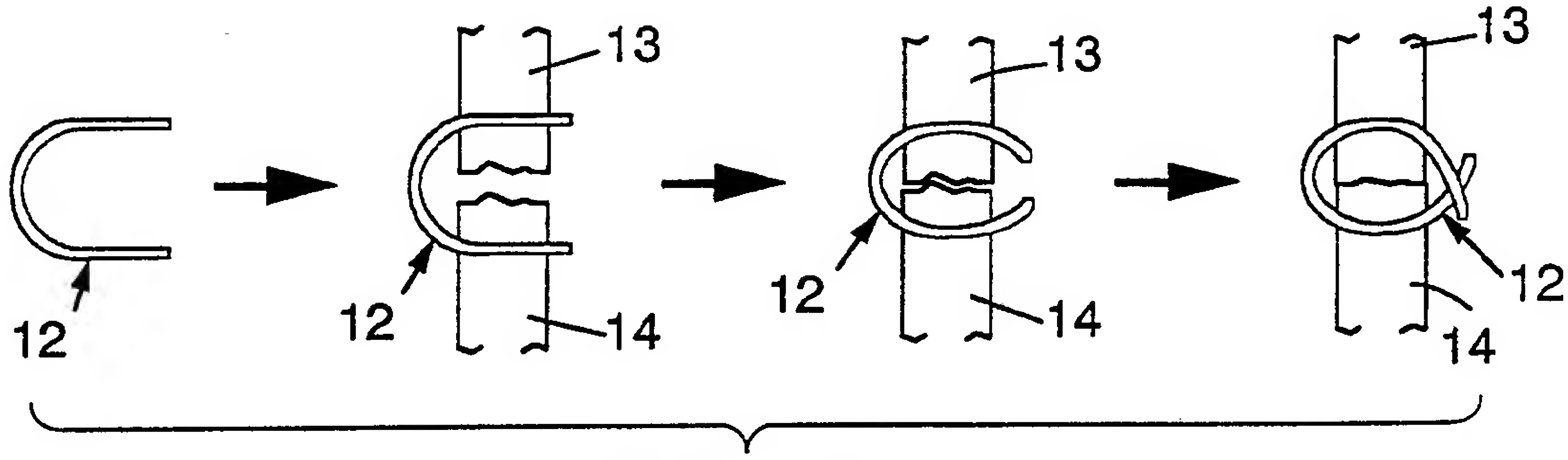


FIG. 26

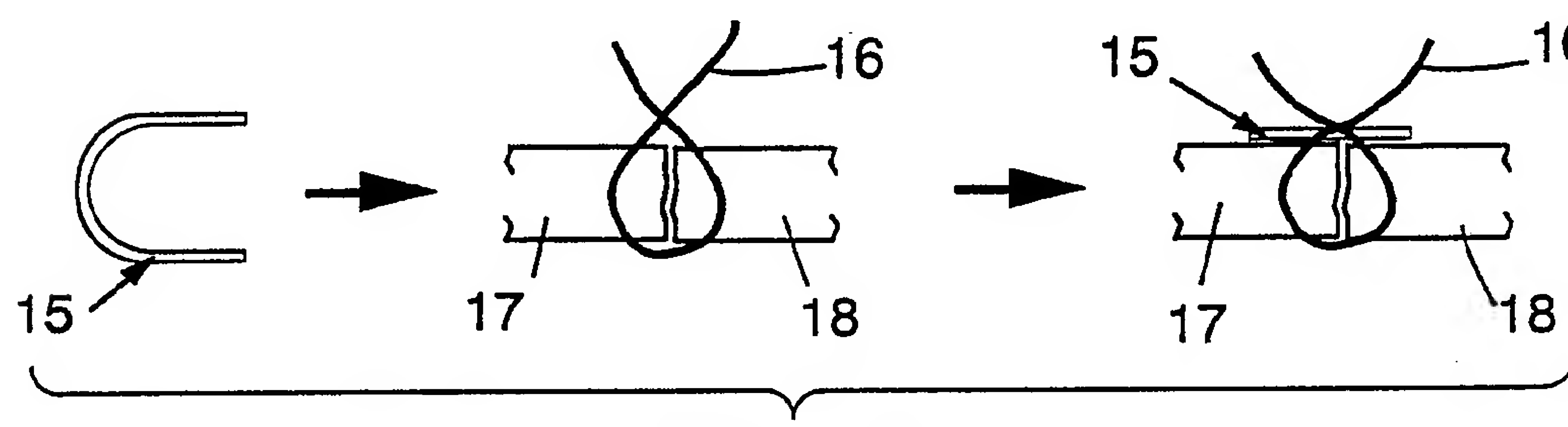


FIG. 27

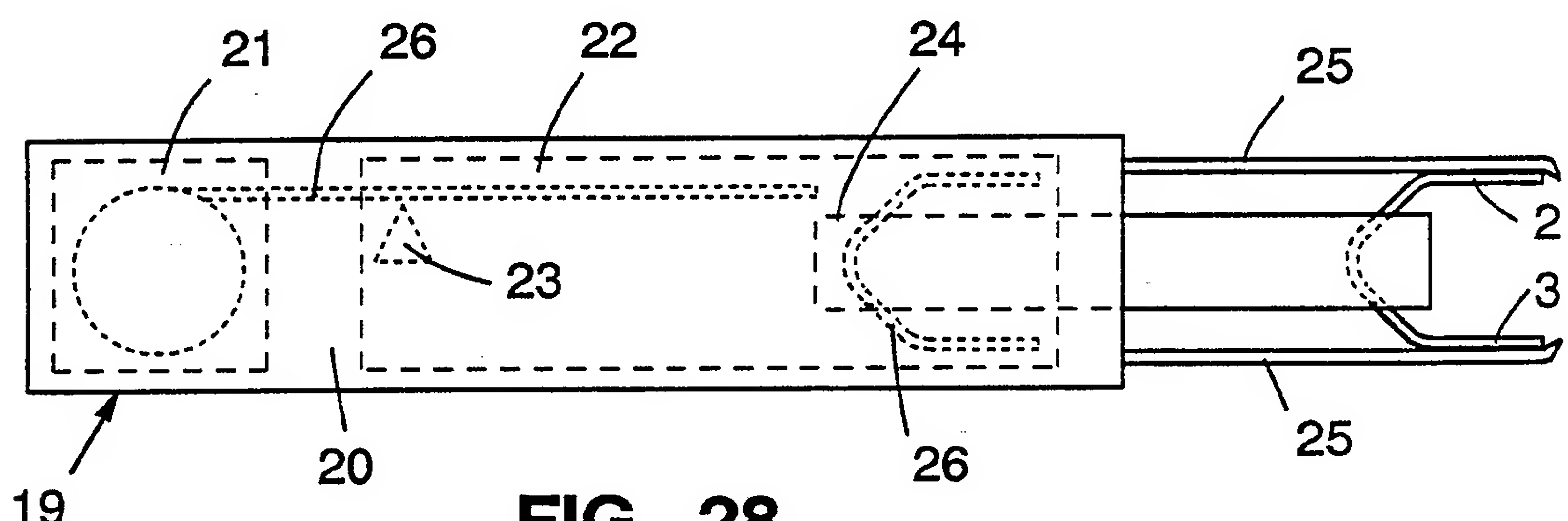


FIG. 28

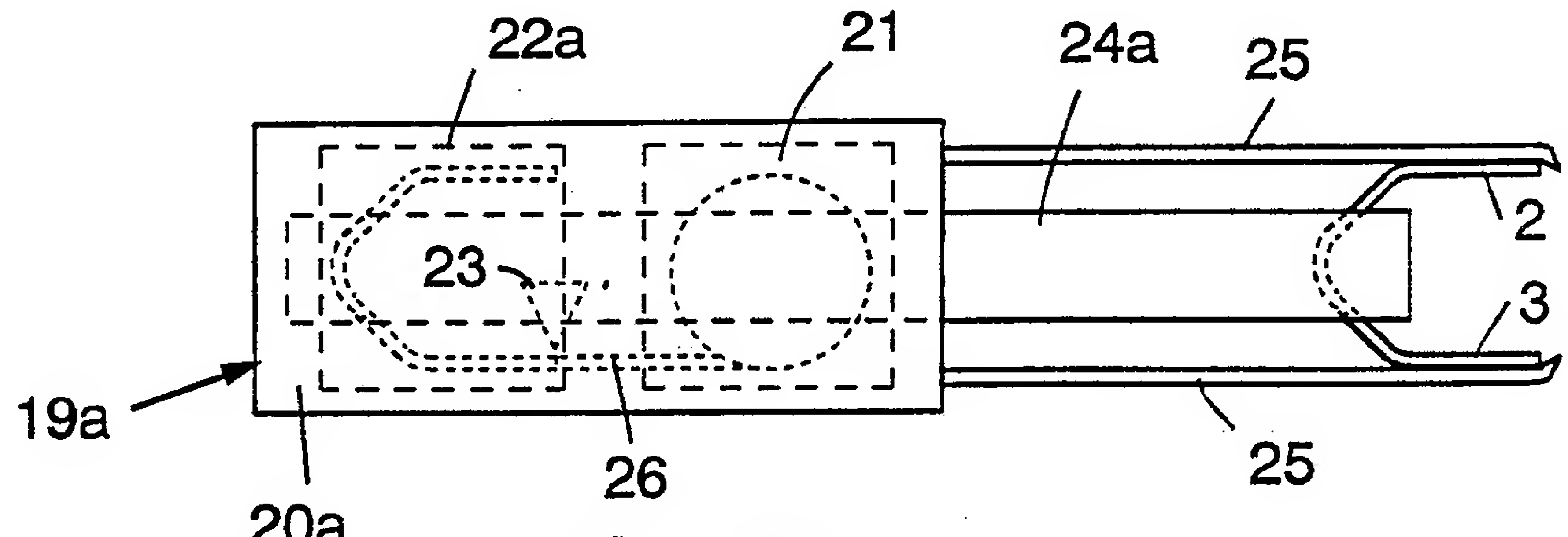


FIG. 29

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00658

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC A61B 17/00
U.S. CL: 606/151

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols	
US	606/158	24/543
	157	545
	151	556

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No [13]
X Y	USA 4 805 618 (VEDA et al.) 21 February 1989 column 2, line 47-column 5, line 17; figures 1-21	1-4,7,21,26-28 39,43-44,46, 48-49 5-6,13-15,17-20
X	USA 4 734543 (NOLF) 29 March 1988 column 4, lines 21-34; column 4, line 53-column 5, line 15; column 10, lines 37-55; figure 7.	1-2,21-22,39 44-45
Y	USA 4 887 335 (FOLKMAR) 19 December 1989 column 1, line 52-column 3, line 12; figures 3-4.	6,13-15,17-20
Y,P	USA 5 026 382 (Peiffer) 25 June 1991 column 3, lines 1-53; figures 3-4	13,17,19
A	USA 4 512 338 (BALKO ET AL) 23 April 1985	50
A	USA 4 665 906 (Jervis) 19 May 1987 ABSTRACT; column 1, line 1- column 4, line 20	1-30,39-57

* Special categories of cited documents: [10]
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20 April 1992	05 JUN 1992
International Searching Authority	Signature of Authorized Officer
ISA/US	Jeffrey A. Schmidt

Form PCT/ISA/210 (second sheet) (Rev.11-87)